HORIBA
Medical

Pentra ES 60

Hematology Analyzer

User Manual

Ref: RAB271AEN

Pentra ES 60

User Manual

CE IVD

HORIBA ABX SAS
B.P. 7290
34184 MONTPELLIER Cedex 4 - FRANCE

User Manual
Ref: RAB271AEN

Contents

Foreword

1. Revisions

Index	Reference	Software Version	Date
A	RAB271AEN	2.5.x	July 2009

This document applies to the latest software version listed and higher versions.

When a subsequent software version changes the information in this document, a new electronic issue (CD-ROM and/or online help) is released and supplied by HORIBA Medical.

To update a paper document, please contact your local HORIBA Medical representative.

2. Legal Information

2.1. Declaration of Conformity

This instrument responds to the Standards and Directives named in the Declaration of Conformity.

Latest version of the CE Declaration of Conformity for this instrument is available on www.horiba.com.

2.2. Notice of Liability

The information in this manual is distributed on an "As Is" basis, without warranty. While every precaution has been taken in the preparation of this manual, HORIBA Medical will not assume any liability to any persons or entities with respect to loss or damage, caused or alleged to be caused directly or indirectly by not following the instructions contained in this manual, or by using the computer software and hardware products described herein in a manner inconsistent with our product labelling.

2.3. Trademarks

Microsoft and Windows are registered trademarks of Microsoft Corporation.

Other product names mentioned within this publication may be trademarks or registered trademarks of their respective owners.

2.4. Graphics

All graphics including screens and printouts, photographs are for illustration purposes only and are not contractual.

2.5. User Manual Symbols

To alert the operator of potentially hazardous conditions, symbols described in this chapter are provided wherever necessary throughout the manual.

Emphasizes information that must be followed to avoid hazard to either the operator or the environment, or both.

Emphasizes information that must be followed to avoid possible damage to the instrument or erroneous test results.

Emphasizes information that can be helpful to the operator before, during or after a specific operational function.

Gives a summary of what can be achieved if the task is performed.

2.6. Copyright ® 2009 by HORIBA ABX SAS

All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of HORIBA Medical.

HORIBA ABX SAS

B.P. 7290

34184 MONTPELLIER Cedex 4 - FRANCE

Phone: +33 (0)4 67 14 15 16

Fax: +33 (0)4 67 14 15 17

Introduction

1. Warning and Precautions

Work safety reliability and general characteristics are guaranteed by HORIBA Medical under the following conditions:

- User manual must be entirely read, and personnel trained by HORIBA Medical before attempting to operate the instrument.
- The user always operates with full knowledge and appreciation of instrument warnings, alarms and flags.
- Always refer to labelling and HORIBA Medical instructions in order to avoid to compromise system integrity.

This instrument must be operated as instructed in the user manual. Any other use might compromise system integrity and might be hazardous for the operator.

This instrument complies with Standards and Directives named in the Declaration of Conformity. The latest version of the Declaration of Conformity for this instrument is available online at www.horiba.com.

- The reagents and accessories stipulated by HORIBA Medical have been validated in accordance with the European Directive for *in vitro* medical devices (98/79/EC).
- The use of any other reagents and accessories may place at risk the performance of the instrument, engaging the user's responsibility. In this case, HORIBA Medical takes no responsibility for the device nor for the results rendered.
- Disposable gloves, eyes protection and lab coat must be worn by the operator.
- Local or national regulations must be applied in all the operations.
- Mobile phones should not be used in proximity of the instrument.
- All peripheral devices should comply with relevant standards.

1.1. Limited Warranty

The duration of warranty is stipulated in the Sales conditions associated with the purchase of this instrument. To validate the warranty, ensure the following is adhered to:

- The system is operated under the instructions of this manual.
- Only software or hardware specified by HORIBA Medical is installed on the instrument. This software must be the original copyrighted version.
- Services and repairs are provided by an HORIBA Medical authorized technician, using only HORIBA Medical approved spare parts.
- The electrical supply of the laboratory adheres to national or international regulations.
- The system is operated according to HORIBA Medical recommendations.
- Specimens are collected and stored in normal conditions.
- Reagents used are those specified in this user manual.
- Proper tools are used when maintenance or troubleshooting operations are performed.

If this instrument has been supplied to you by anyone other than HORIBA Medical or an authorized representative, HORIBA Medical cannot guarantee this product in terms of specification, latest revision and latest documentation. Further information may be obtained from your authorized representative.

1.2. Safety Precautions

1.2.1. Electronic and Moving Parts

The following parts must not be handled or checked by the user:

- Electrical Power supply
- Electronic circuit boards

Operator injury may occur from an electric shock. Electronic components can shock and injure the user. Do not dismantle the instrument nor remove any components (covers, doors, panels and so on) unless otherwise instructed within this document.
Danger of explosion if battery is not replaced correctly! When replacing the battery, always use the same and/or equivalent type recommended by the manufacturer. Dispose of used batteries according to the manufacturer's specific instructions.

Moving parts: It is strictly forbidden to disable sensors as it may cause operator injuries. Protection covers must not be opened during instrument operations. Opening the doors and covers during instrument operations causes the instrument emergency stop.

1.2.2. Biological Risk

Consider all specimens, reagents, calibrators, controls, etc.… that contain human specimens extracts as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other biosafety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.

All accessible surfaces of the instrument can be potentially contaminated by human specimens. Disposable gloves and lab coat must be worn by the operator. Local and national regulations must be applied in all the operations.

The manufacturer uses disinfectant product for instrument decontamination and highly recommends it to decontaminate your instrument. See *Maintenance* > *To Decontaminate your Instrument* chapter to perform the instrument cleaning and decontamination procedure.

See also:
- To Decontaminate your Instrument, p.165

1.3. Graphics and Symbols


Switch off position

Switch on position


Alternating current


Manufacturer

In Vitro Diagnostic medical device


This product conforms to the EC Directives named in the Declaration of Conformity


Caution, consult accompanying documents


Biological risk

Reagent


Up


Fragile, handle with care


Keep dry


Do not stack


Temperature limitation

Batch code

Catalogue number


Use by


Consult Instruction for Use

Calibrator

Control

CONT. Content

Use no hooks

Highly flammable

Toxic

This product should be disposed of and recycled at the end of the useful life in accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.

Notice of environment-friendly use period

Packaging recycling mark

Ground

Electostatic Sensitive Device (ESD)

2. Operational Conditions

2.1. Environment

The operation of the Pentra ES 60 should be restricted to indoor location use only!

Instrument is operational at an altitude of maximum 3000 m (9840 ft).

The instrument is designed for safety from voltages surges according to INSTALLATION CATEGORY II and POLLUTION DEGREE 2 (IEC 61010-1).

Please contact your local representative for information regarding operation locations, when it does not comply with the recommended specifications.

2.2. Location

- Place your instrument on a clean and leveled table or workbench.

Keep in mind that the instrument weighs approximately 35 Kgs (77 lbs).

- Avoid exposure to sunlight.
- Place your instrument where it is not exposed to water or vapor.
- Place your instrument where it is free from vibration or shock.
- Place your instrument where an independent power receptacle can be used.
- Use a receptacle different from the one used by a device that easily generates noise such as a centrifuge, etc.
- Provide a space of at least 20 cm (8 in.) at the back of the instrument for a proper ventilation and an easy access to connections.

The Power switch and Power supply connection should always be accessible! When positioning the system for operational use, leave the required amount of space for easy accessibility to these items.

2.3. Grounding

Proper grounding is required when installing the system. Check the wall outlet ground (earth) for proper grounding to the facilities electrical ground. If you are unsure of the outlet grounding, contact your facilities engineer to verify the proper outlet ground.

2.4. Humidity and Temperature Conditions

Instrument operating temperature: from +16°C (+61°F) to +34°C (+93°F), with a relative humidity of 80% maximum, without condensation. If the instrument is stored at a temperature lower than 10°C (50°F), it should stand for one hour at a normal room temperature before use.

Temperature gradient: 2°C.

2.5. Electromagnetic Environment Check

The instrument has been designed to produce less than the accepted level of electromagnetic interference in order to operate in conformity with its destination, allowing the correct operation of other instruments also in conformity with their destination.

In case of suspected electromagnetic noise, check that the instrument has not been placed in the proximity of electromagnetic fields or short wave emissions, e.g. Radar, X-rays, Scanners, Cell phones, etc.

2.6. Main Power Supply

Grounding is required. Check that earth wall-plug is correctly connected to the laboratory grounding system. If there is no such system, a ground stake should be used.

Use only main supply cable delivered with the instrument.

Main power supply voltage fluctuations must not exceed +/- 10% of the nominal voltage.

Connections to supply have to be done by your local representative.

See also:
- Grounding, p.15
- Power Requirements, p.28

2.7. Environmental Protection

Used Accessories and Consumables Disposal

Disposable used accessories and consumables must be collected by a laboratory specialized in elimination and recycling of this kind of material according to the local legislation.

Instrument Disposal

This product should be disposed of and recycled at the end of the useful life in accordance with European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and/or European Directive 2006/66/EC on batteries and accumulators.

If any doubt, please contact your local representative.

2.8. Storage Conditions and Transportation

Instrument storage temperatures: from -20°C (-4°F) to +50°C (+122°F).

Prior to the shipping of an instrument by transporter, whatever the destination, an external decontamination of the instrument must be carried out.

Before instrument removal from use, transportation or disposal, perform a general cleaning and a draining of your instrument.

See also:
- To Drain Chambers, p.174

2.9. Installation

A representative will install your instrument, printer and software.

Package content:

- Pentra ES 60
- Power supply cable
- User Manual CD-ROM
- Daily Guide
- Reagents, Controls & Calibrators CD-ROM

- Installation kit
- Workstation
- Computer keyboard
- Computer mouse
- Printer
- Waste tank

3. Labels and Connections

3.1. Serial Number Label

3.2. Power Supply Connection

The Power switch and Power supply connection should always be accessible! When positioning the system for operational use, leave the required amount of space for easy accessibility to these items.

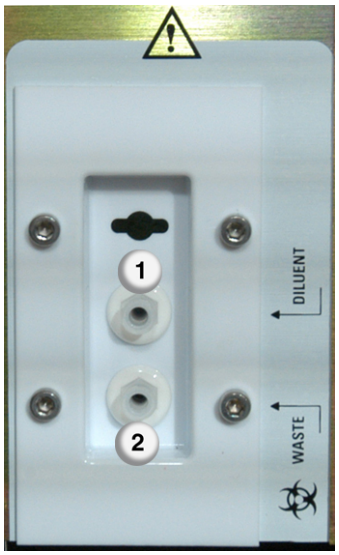
1 = Power supply connector

2 = ON/OFF switch

3.3. Diluent and Waste Connections

1 = ABX Diluent input

2 = Waste output



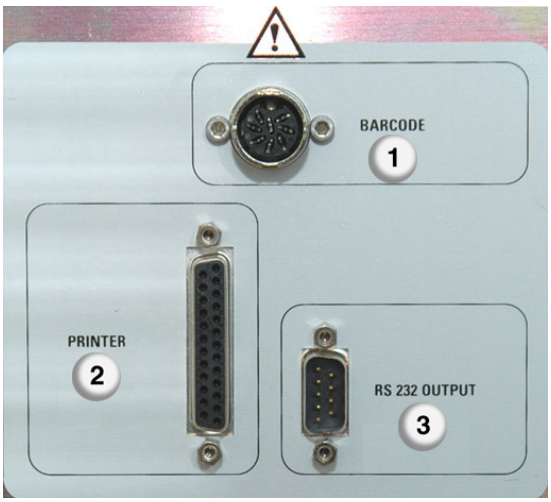
Waste must be handled according to your local and/or national regulations.

3.4. Peripherals Connections

1 = Barcode reader (not used)

2 = Printer (not used)

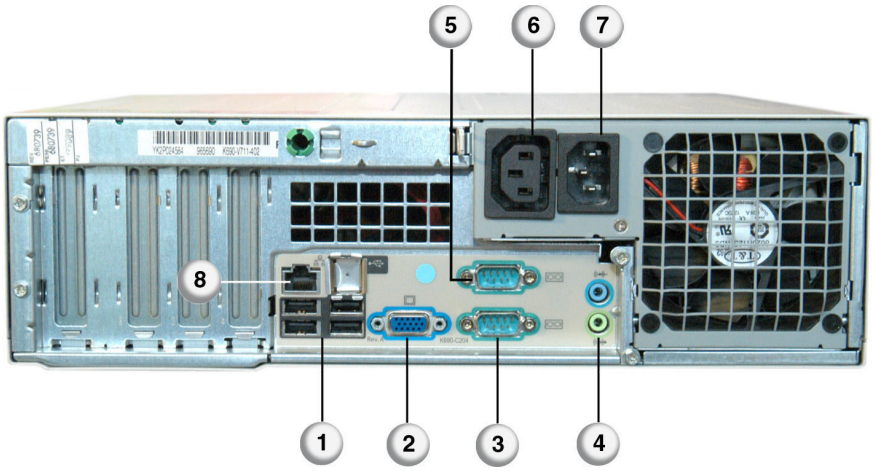
3 = Serial port (RS232)



Printer and barcode reader have to be connected to the Workstation's USB ports. See *Computer Connections* chapter.

All peripheral devices should comply with relevant standards.

3.5. Computer Connections



1 = USB (Keyboard, Mouse, Printer, Barcode reader)

2 = Monitor

3 = Serial port used used for **instrument** connection

4 = Hi-speakers (not used)

5 = Serial port used for **LIS** connection

6 = Power Supply (Male cord)

7 = Power Supply (Female cord)

8 = Network RJ 45

3.6. Warnings and Biological Risks Labels

Definition	Location	Symbol
Warning, biological hazard	Right-hand side of the instrument	
General warning, caution, risk of danger	Back of the instrument	

4. Printer

Use the printer supplied or approved by HORIBA Medical.

The user must check the printer compatiblility with the Pentra ES 60. A list of compatible printers is available on the documentation database (*Other* > *printers*) at www.horiba.com .

See also:
- To Switch On the Printer, p.74
- Printer Operation Problems, p.178

Specifications

1. Technical Specifications

1.1. Intended Use

This instrument is a fully automated hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

The instrument can operate in:

- CBC mode (Cell Blood Count)
- DIF mode (CBC + 5 population Differential count)

A control station (Workstation) is directly connected to the instrument and:

- drives the instrument: orders and cycle requests are sent from the station to the instrument,
- collects and manages data received from the instrument,
- can be connected to a LIS system.

1.2. Parameters

CBC Parameters	Definition
WBC	White Blood Cells
RBC	Red Blood Cells
HGB	Hemoglobin concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Distribution Width
PLT	Platelets
PDW *	Platelets Distribution Width
PCT *	Plateletcrit
MPV	Mean Platelet Volume

DIF Parameters	Definition
LYM #	Lymphocytes absolute value
LYM %	Lymphocytes percentage
MON #	Monocytes absolute value
MON %	Monocytes percentage
NEU #	Neutrophils absolute value

DIF Parameters	Definition
NEU %	Neutrophils percentage
EOS #	Eosinophils absolute value
EOS %	Eosinophils percentage
BAS #	Basophils absolute value
BAS %	Basophils percentage
ALY # *	Atypical Lymphocytes absolute value
ALY % *	Atypical Lymphocytes percentage
LIC # *	Large Immature Cells absolute value
LIC % *	Large Immature Cells percentage

* PDW, PCT, ALY#, ALY%, LIC#, LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

1.3. Throughput Analyses

The rate of analysis for the Pentra ES 60 is of 60 samples per hour.

1.4. Tube Identification

Tube identification can be done either by using:

- An external keyboard
- An external barcode reader (optional)

1.5. Computer Characteristics

- Color Screen 15 in. (800 x 600px)
- Windows XP Prof.™
- Capacity: 10 000 results + graphics
- Hard drive: 2 partitions
- CD-ROM drive / Floppy Disk
- 2 serial ports minimum
- USB Keyboard / USB Mouse
- Communication protocols : ABX / ASTM

Pentra ES 60 workstation application has been validated by HORIBA Medical with Operating System: "MS Windows XP Prof.™" only. The use of any other Operating System might compromise system integrity engaging the users' reponsibility. In this case, HORIBA Medical takes no responsibility for the device nor for the results rendered. The installation of Pentra ES 60 application on any personal computer requires specific settings that must be performed by an HORIBA Medical approved technician.

1.6. Measurements and Computation

- RBC, PLT = Impedance
- WBC, BAS = Impedance
- LYM, MON, NEU, EOS, ALY, LIC = Impedance and absorbance
- HGB = Photometry
- HCT = Numeric Integration
- MCV, MCH, MCHC, RDW, PDW, PCT, MPV = Calculation

1.7. Units

CBC Parameters	Standard	SI (international)	mmol/L	Japan
WBC	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/mm^3$
RBC	$10^6/mm^3$	$10^{12}/L$	$10^{12}/L$	$10^4/mm^3$
HGB	g/dL	g/L	mmol/L	g/dL
HCT	%	L/L	L/L	%
MCV	μm^3	fL	fL	μm^3
MCH	pg	pg	fmol	pg
MCHC	g/dL	g/L	mmol/L	g/dL
RDW	%	%	%	%
PLT	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^4/mm^3$
PDW *	%	%	%	%
PCT *	%	$10^{-2}/L$	$10^{-2}/L$	%
MPV	μm^3	fL	fL	μm^3

DIF Parameters	Standard	SI (international)	mmol/L	Japan
LYM#	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
LYM%	%	%	%	%
MON#	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
MON#	%	%	%	%
NEU#	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
NEU%	%	%	%	%
EOS#	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
EOS%	%	%	%	%

DIF Parameters	Standard	SI (international)	mmol/L	Japan
BAS#	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
BAS%	%	%	%	%
ALY# *	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
ALY% *	%	%	%	%
LIC# *	$10^3/mm^3$	$10^9/L$	$10^9/L$	$10^2/\mu L$
LIC% *	%	%	%	%

* PDW, PCT, ALY#, ALY%, LIC#, LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

See also:
- Units and Language, p.136

2. Physical Specifications

2.1. Power Requirements

- Power supply: from 100 V to 240 V (+/- 10%), 50 Hz to 60 Hz
- Maximum power consumption: 400 VA (Instrument and workstation)
- Maximum heat output: 1440 kJ/h (1365 BTU/h)
- Printer: refer to your printer's manual.
- Workstation: refer to your computer's manual.

See also:
- Grounding, p.15
- Main Power Supply, p.15

2.2. Humidity and Temperature Conditions

Instrument operating temperature: from +16°C (+61°F) to +34°C (+93°F), with a relative humidity of 80% maximum, without condensation. If the instrument is stored at a temperature lower than 10°C (50°F), it should stand for one hour at a normal room temperature before use.

Temperature gradient: 2°C.

2.3. Dimension and Weight

- Instrument dimensions: 44.5 x 48 x 51.5 cm (Width x Depth x Height)
- Instrument weight: 35 Kgs (77 lbs)
- Workstation dimensions and weight: refer to your computer's manual

2.4. Minimum Specimen Volume

Quantity of whole blood aspirated:

- CBC mode: 30 µL
- DIF mode: 53 µL

2.5. Dilution Ratio

Parameter	Dilution ratio
RBC/PLT	1/10000
WBC/BAS	1/200
LMNE	1/80
HGB	1/250

2.6. Counting Aperture Diameters

Parameter	Aperture diameter
RBC/PLT	50 µm
WBC/BAS	80 µm
LMNE	60 µm

3. Summary of Performance Data

3.1. Precision (Reproducibility)

Source: 510K submission K030144

The instrument was initially calibrated with the ABX Minocal calibrator (Lot N° CX322).

Three levels of ABX Minotrol 16 material (Lot N° JX108) were run once a day for a prolonged period on all parameters. The results were used to quantify the Within Run precision, and the Total Precision in accordance with the CLSI EP 5-A Guidelines.

Parameter	ABX Minotrol Control	Within Run SD	SD of Run Means	SD of Daily Means	Total precision (SD)
WBC	JX108 Low	0.001	N/A	N/A	0.001
	JX108 Normal	0.008	N/A	N/A	0.013
	JX108 High	0.031	N/A	N/A	0.045
RBC	JX108 Low	0.000	N/A	N/A	0.000
	JX108 Normal	0.001	N/A	N/A	0.001
	JX108 High	0.002	N/A	N/A	0.003
HGB	JX108 Low	0.001	N/A	N/A	0.001
	JX108 Normal	0.002	N/A	N/A	0.007
	JX108 High	0.005	N/A	N/A	0.0012
HCT	JX108 Low	0.021	N/A	N/A	0.025
	JX108 Normal	0.064	N/A	N/A	0.122
	JX108 High	0.104	N/A	N/A	0.181
PLT	JX108 Low	6.271	N/A	N/A	20.646
	JX108 Normal	40.229	N/A	N/A	72.103
	JX108 High	154.146	N/A	N/A	381.388

Parameter	ABX Minotrol Control	Within Run CV%	CV% of Run Means	CV% of Daily Means	Total precision (CV%)
WBC	JX108 Low	1.8	N/A	N/A	1.93
	JX108 Normal	0.9	N/A	N/A	1.12
	JX108 High	0.9	N/A	N/A	1.05
RBC	JX108 Low	0.8	N/A	N/A	0.86
	JX108 Normal	0.6	N/A	N/A	0.79
	JX108 High	0.7	N/A	N/A	0.88
HGB	JX108 Low	0.4	N/A	N/A	0.57
	JX108 Normal	0.3	N/A	N/A	0.59
	JX108 High	0.4	N/A	N/A	0.60

Parameter	ABX Minotrol Control	Within Run CV%	CV% of Run Means	CV% of Daily Means	Total precision (CV%)
HCT	JX108 Low	0.9	N/A	N/A	0.99
	JX108 Normal	0.7	N/A	N/A	0.97
	JX108 High	0.7	N/A	N/A	0.89
PLT	JX108 Low	3.1	N/A	N/A	5.69
	JX108 Normal	2.6	N/A	N/A	3.46
	JX108 High	2.5	N/A	N/A	4.01

Expected Precision on control samples

Parameters	Low level	Normal level	High level
WBC	5%	4%	3%
RBC	3%	2.5%	2.5%
HGB	2.5%	2%	1.8%
HCT	5%	4%	3%
MCV	3%	2.5%	2%
RDW	5%	5%	5%
PLT	15%	10%	7%
LYM%	8%	8%	8%
MON%	70%	40%	30%
NEU%	8%	6%	4%
EOS%	15%	13%	10%
BAS%	8%	8%	8%

See also:
- Glossary of Terms, p.206

3.2. Precision Claims

Based on ten consecutive runs without alarm of the same fresh whole blood sample:

Parameter	CV%	Nominal Values
WBC	< 2%	4 - 10 x 10^3/mm^3
RBC	< 2%	3.6 - 6.2 x 10^6/mm^3
HGB	< 1%	12 - 18 g/dL
HCT	< 2%	36 - 54 %
PLT	< 5%	150 - 500 x 10^3/mm^3

See also:
- Repeatability Overview, p.64
- To Perform a Repeatability, p.65

3.3. Linearity Limits

Source: 510K submission K030144

Linearity range: the manufacturer's tested linearity zone of the instrument using linearity kits and/or human blood.

Linearity limits: maximum and minimum values within instrument returns no dilution alarm.

Visible range: range values given by the instrument. These values (above linearity limits) are given as an indication. They are associated to a "D" flag. This visible range is outside manufacturer range.

Linearity kits: linearity was tested using available «Low Range» and «Full Range» linearity test kits. The test kits were analyzed and data was computed according to the manufacturer's instructions.

Human Blood: linearity was also obtained on human blood, using a minimum of 5 dilution points. The results of this study are as follows:

Parameter	Linearity Range	Linearity Limits	Visible Range	Error Limit
WBC (10^3/mm^3)	0.40 to 130.80	0 to 120	120 to 150	± 0.3 / ± 7.5%
RBC (10^6/mm^3)	0.23 to 9.76	0 to 8	8 to 18	± 0.07 / ± 3%
HGB (g/dL)	0 to 31.06	0 to 24	24 to 30	± 0.3 / ± 3%
HCT (%)	1.80 to 88.90	0 to 67	67 to 80	± 2 / ± 3%
PLT (10^3/mm^3) for HGB ≥ 2g/dL	3.30 to 2007	0 to 1900	1900 to 2800	± 10 / ± 12.5%
PLT (10^3/mm^3) for HGB < 2g/dL & PLT > 15x10^3/mm^3	7 to 2895	0 to 2800	2800 to 3200	± 10 / ± 12.5%

See also:
- Glossary of Terms, p.206
- Results Exceeding Instrument Capacities, p.34

3.4. Carry-over

Source: 510K submission K030144

The Pentra ES 60 carry-over effects were evaluated by running a sample with high cell concentration three consecutive times (H1-H3), then running a diluted sample consecutively 3 times (L1-L3).

Carry-over = (L1-L3) / (H3-L3) x 100

	WBC (10^3/mm^3)	RBC (10^6/mm^3)	HGB (g/dL)	PLT (10^3/mm^3)
Mean Low level	1.06	1.58	5.28	31.33
Mean High level	58.81	6.37	22.03	1106.67
Actual Carry-over (%)	-0.26	0	-0.179	-0.186
Claimed Carry-over (%)	< 2%	< 2%	< 2%	< 2%

Method described in *Guidelines for the Evaluation of Blood Cell Analyzers including those used for Differential Leukocyte and Reticulocyte Counting and Cell Marker Applications*. ISLH, 14 January, 1994.

See also:
- Glossary of Terms, p.206

3.5. Normal Ranges

Parameters	Male	Female
WBC ($10^3/mm^3$)	4 - 10	4 - 10
RBC ($10^6/mm^3$)	4.5 - 6.5	3.8 - 5.8
HGB (g/dL)	13.0 - 17.0	11.5 - 16.0
HCT (%)	40 - 54	37 - 47
MCV (μm^3)	80 - 100	80 - 100
MCH (pg)	27.0 - 32.0	27.0 - 32.0
MCHC (g/dL)	32.0 - 36.0	32.0 - 36.0
RDW (%)	11.0 - 16.0	11.0 - 16.0
PLT ($10^3/mm^3$)	150 - 500	150 - 500
MPV (μm^3)	6 - 11	6 - 11
PCT (%) *	0.15 - 0.5	0.15 - 0.5
PDW (%) *	11 - 18	11 - 18
LYM (%)	25 - 50	25 - 50
MON (%)	2 - 10	2 - 10
NEU (%)	50 - 80	50 - 80
EOS (%)	0 - 5	0 - 5
BAS (%)	0 - 2	0 - 2

* PDW, PCT, ALY#, ALY%, LIC#, LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

Expected values may vary with sample population and/or geographical location. It is highly recommended that each laboratory establishes its own normal ranges based upon the local population.

3.6. Accuracy

Source: 510K submission K030144

The data shows a good correlation between the results obtained on Pentra ES 60 and the reference system:

Parameter	R (comparison of means)	Accuracy Claims
WBC	0.9956	> 0.95
PLT	0.9978	> 0.95
RBC	0.9965	> 0.95
HGB	0.9985	> 0.95
HCT	0.9992	> 0.95
LYM	0.9937	> 0.95
NEU	0.9946	> 0.95
MON	0.9872	> 0.95
EOS	0.9864	> 0.95

See also:
- Glossary of Terms, p.206

3.7. Results Exceeding Instrument Capacities

Use the instrument's diluent to dilute the sample if a "---- D" flag occurs on WBC or HCT.

Parameter	Linearity Limits	Visible Range	> Visible Range (displayed)	> Visible Range (transmitted or printed out)
WBC	«result»	«result+D»	DIL	--.-- + D
RBC	«result»	«result+D»	DIL	--.-- + D
HGB	«result»	«result+D»	DIL	--.-- + D
HCT	«result»	«result+D»	DIL	--.-- + D
PLT	«result»	«result+D»	DIL	--.-- + D

Results displayed and printed out: «PLT-C» indicates the triggering of the PLT extended linearity mode for an HGB < 2g/dL & PLT > 15 x 10^3/mm^3 between 1900 x 10^3/mm^3 and 2800 x 10^3/mm^3.

Results transmitted: «C» indicates the triggering of the PLT extended linearity mode for an HGB < 2g/dL & PLT > 15 x 10^3/mm^3 between 1900 x 10^3/mm^3 and 2800 x 10^3/mm^3.

See *Workflow* > *Results Interpretation* chapter to know more about these flags.

Whole blood parameter results within visible range will still give a result value with a "**D**" flag. These results require a dilution (or PRP analysis for PLT) of the sample with the instrument's diluent.

See also:
- PLT-C Flag, p.118
- Linearity Limits, p.32

4. Sample Collection and Mixing

All blood samples should be collected using proper technique!

Consider all specimens, reagents, calibrators, controls, etc.… that contain human specimens extracts as potentially infectious! Use established, good laboratory working practices when handling specimens. Wear protective gear, gloves, lab coats, safety glasses and/or face shields, and follow other biosafety practices as specified in OSHA Blood borne Pathogens Rule (29 CFR part 1910. 1030) or equivalent biosafety procedures.

When collecting blood specimens, venous blood is recommended, but arterial blood may also be used in extreme cases. Blood collection must be placed in vacuum or atmospheric collection tubes.

For additional information on collecting venous and capillary blood samples, refer to CLSI document H3-A6 (dec. 2007) and CLSI document H4-A5 (june 2004).

The sample collection tube has to be filled to the exact quantity of blood indicated on the tube itself. Any incorrectly measured blood sample collections will show a possible variation in the results.

4.1. Recommended Anticoagulant

The recommended anticoagulant is K3EDTA with the proper proportion of blood to anticoagulant as specified by the tube manufacturer.

K2EDTA is an acceptable alternative, as long as the sample collection is made in normal conditions. Otherwise, blood clots may be possible.

4.2. Blood Sample Stability

Sample stability at low temperature

Ten «normal» and ten «pathological» specimens were collected from the routine laboratory workload and stored at 4°C. Sample stability was assessed over a period of 72 hours. The results (mean of ten consecutive tests) conclude with a relative sample stability claim of 48 hours for the CBC parameters and 24 hours for the DIF parameters.

Sample stability at room temperature

Ten «normal» and ten «pathological» specimens were collected from the routine laboratory workload and stored at room temperature (25°C). Sample stability was assessed over a period of 72 hours. The results (mean of ten consecutive tests) conclude with a relative sample stability claim of 48 hours for the CBC parameters and 24 hours for the DIF parameters.

4.3. Microsampling

Instrument sampling mode enables the user to work with 100 µL microsamples (for pediatrics and geriatrics).

On microsampling tubes, the 100 µL volume can only be used in the following conditions:

- The tube must always be held in vertical position.
- Blood mixing must be obtained by slight tapping on the tube. Do not rotate the tube for mixing, otherwise the blood will be spread on the tube side, and the minimum required level will be lost.

4.4. Mixing

Blood samples must be gently and thoroughly mixed just before sampling. This ensures a homogeneous mixture for measurement.

5. Reagents Specifications

In order for the instrument to operate correctly, high-quality reagents must be used.
HORIBA Medical provides a full range of reagents.
These reagents are used for *in vitro* diagnostic.

All these reagents are manufactured by:
HORIBA ABX SAS
B.P. 7290
34184 MONTPELLIER Cedex 4 - FRANCE
Phone: +33 (0)4 67 14 15 16
Fax: +33 (0)4 67 14 15 17

Refer to the reagent notices for Pentra ES 60 available online at www.horiba.com.

The reagents specified for this instrument have been approved in accordance with the European Directive 98/79/EC (Annex III) for *in vitro* medical devices.

HORIBA Medical manufactures and markets reagents, calibrators and control bloods specially designed for use with this analyzer. The use of products not recommended may give erroneous results or instrument operation problems. For all information regarding the recommended products, please contact your local representative.

5.1. Reagents Location

Locate the instrument reagent bottles, the diluent container and the waste container.

All the reagent bottles are installed into the instrument reagent compartment.
Diluent and waste containers are on the floor below the instrument.

1 = ABX Cleaner

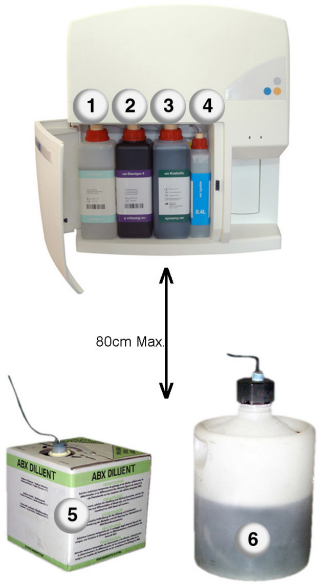
2 = ABX Basolyse II

3 = ABX Eosinofix

4 = ABX Lysebio / ABX Alphalyse

5 = ABX Diluent

6 = Waste container



Risk of erroneous results if the diluent container is installed further than 80 cm (32 in.) below the instrument.

Diluent input tubing: cristal 3x6 / 2 meters (80 in.) maximum.
Waste output tubing: cristal 4x6 / 2 meters (80 in.) maximum.

5.2. Reagents Description

Pentra ES 60 must be used exclusively with the following reagents:

- ABX Diluent (10 Liters or 20 Liters) : for RBC/PLT dilution, sleeving and cleaning.
- ABX Cleaner (1 Liter, integrated) : for cleaning.
- ABX Basolyse II (1 Liter, integrated) : for WBC/BAS differentiation + WBC counting reference.
- ABX Eosinofix (1 Liter, integrated) : for LMNE and immatures differentiation.
- ABX Lysebio / ABX Alphalyse (1 Liter, integrated) : for hemoglobin measurement.
- ABX Minoclair (0,5 Liter, non-integrated) : for concentrated cleaning procedure.

See also:
- Reagents Location, p.37
- Reagent Notices, p.39
- Instrument Reagent Consumption, p.39
- Waste Handling Precautions, p.40
- To Replace the Diluent Container, p.159
- To Replace a Reagent Bottle, p.161
- To Prime Reagents, p.163
- To Replace the Waste Container, p.164

5.3. Instrument Reagent Consumption

Reagent consumption is given in mL per cycle.

Cycles	ABX Diluent	ABX Basolyse II	ABX Cleaner	ABX Eosinofix	ABX Lysebio / ABX Alphalyse	Duration
CBC	20.4	2.1	0.9	X	0.4	60"
DIF	25.6	2.1	0.9	1	0.4	60"
Startup	60.8	2.1	3.7	1	1.4	3'53"
Shutdown	20.5	X	14	X	1	2'48"
Prime ABX Diluent	42.9	X	X	X	X	3'03"
Prime ABX Cleaner	1.1	X	24.8	X	X	1'22"
Prime ABX Eosinofix	1.6	X	X	23.6	X	1'12"
Prime ABX Basolyse II	1.1	23.6	1.1	X	X	1'20"
Prime ABX Lysebio / ABX Alphalyse	2.1	X	X	X	8.4	1'27"
Prime all reagents	47	24	25.1	24	8.2	6'
Autoclean cycle	14.2	1	1	1	0.3	1'38"
Autocontrol cycle	23.4	X	1.4	X	1	1'04"
RBC chamber cleaning	2.5	X	X	X	X	7"
Unprime all	X	X	X	X	X	6'25"
Chambers rinsing	12.6	1	1	1	0.3	1'17"
Cytometer rinsing	4.9	X	X	X	X	1'11"
Concentrated cleaning	25	X	1.4	X	0.9	4'10"
Cleaning	12.6	1	1	1	0.3	1'19"

5.4. Reagent Notices

The CD-ROM RAX055 delivered with your instrument provides Reagents, Controls and Calibrators leaflets / MSDS. Latest versions of these documents are available online at www.horiba.com.

5.5. Waste Handling Precautions

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubes and the liquid waste tube under any condition.

- If required, waste can be neutralized before being discarded. Follow your laboratory's protocol when neutralizing and disposing of waste.
- Dispose of the waste container according to your local and/or national regulatory requirements.

See also:
- To Replace the Waste Container, p.164
- To Check the Waste Container Level, p.74

6. Limitations

While every effort is taken by HORIBA Medical to investigate and indicate all known interferences, it is not possible to guarantee that all interferences have been identified. At all times, results should be validated and communicated only once all information relating to the patient has been assessed and taken into account.

6.1. Maintenance

In *Maintenance & Troubleshooting* section, specific maintenance procedures are listed. The maintenance procedures identified are mandatory for proper use and operation of the Pentra ES 60.

Failure to execute any of these recommended procedures may result in poor reliability of the system.

6.2. Blood Specimens

Verification of any abnormal test result (including flagged results or results outside of the normal range) should be performed using reference methods or other standard laboratory procedures for conclusive verification of the results. The chapter hereunder lists known limitations of automated blood cell counters, which use the principles of impedance and light absorbance as principles of measurement.

6.3. Known Interfering Substances

6.3.1. Interferences on White Blood Cells (WBC)

Unlysed red blood cells: in certain cases of membrane resistance, partial lysis of red blood cells may be observed. These unlysed red blood cells may cause an erroneously high white blood cell count. These unlysed red cells can be detected on the WBC curve via an L1 alarm or in the form of an elevated base line of the lateral ascending section of the lymphocyte population.

Multiple myeloma: the precipitation of immunoglobulins in patients with multiple myeloma may give elevated WBC counts.

Hemolysis: hemolyzed specimens contain an erythrocyte stroma, which may cause elevated white blood cell counts.

Platelet agglutination: the accumulation of platelets may cause an elevated white blood cell count. Platelet agglutination triggers the alarms L1, LL, and LL1.

Leukemia: leukemia can cause fragility of the leukocytes and subsequent destruction of these cells during the count, thus resulting in an abnormally low white blood cell count. These leukocytic fragments may also interfere with the various parameters of the differential white cell count. An abnormally low leukocyte count may also be seen in patients with chronic lymphoblastic leukemia due to the presence of abnormally small lymphocytes, which may not be counted by the analyzer.

Chemotherapy: cytotoxins and immunosuppressants may weaken the leukocyte membranes and result in a low leukocyte count. In these particular cases, CBC mode must not be used as WBC balance alarm is disabled. It is recommended to run these samples in DIF mode.

Cryoglobulins: the increased levels of cryoglobulins that may be associated with various conditions (myeloma, carcinoma, leukemia, macroglobulinema, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, aneurysms, pregnancy, thromboembolic phenomena, diabetes, etc.), may cause an increase in the leukocyte, erythrocyte, and platelets counts and the hemoglobin concentration. The samples should be warmed to 37°C (99°F) in a water bath for 30 minutes and then re-run immediately afterwards (using the analyzer or a manual method).

Macrothrombocytes: in excessive numbers, they may affect the leukocyte count by increasing the number of leukocytes counted.

Erythroblasts: high concentrations of erythroblasts may increased the leukocyte count.

6.3.2. Interferences on Red Blood Cells (RBC)

The red blood cell dilution contains all of the elements found in the blood: erythrocytes, leukocytes, and platelets. During the erythrocyte count, the platelets are not counted as they are smaller than the defined minimum threshold. In very rare cases with an extremely high leukocyte count, the erythrocyte count may be increased. It should be corrected, especially if the latter is very low in comparison with the leukocyte count.

Agglutinated red blood cells: these may cause a falsely low RBC count. Blood samples containing agglutinated red blood cells can be identified by abnormal MCH and MCHC values and the examination of a stained blood smear.

Cold agglutinins: IgM, which are elevated in Cold Agglutinin Disease, may lower erythrocyte and platelet counts and increase the MCV. The samples should be warmed to 37°C (99°F) in a water bath for 30 minutes and then re-run immediately afterwards (using the analyzer or a manual method).

6.3.3. Interferences on Hemoglobin (HGB)

Turbidity of the blood sample: several physiological and/or therapeutic factors may produce falsely elevated hemoglobin results. To obtain accurate results in blood samples with increased turbidity, determine the cause of the turbidity and follow the appropriate method below:

- An elevated leukocyte count: a very high leukocyte count will cause excessive diffusion of the light. In such cases, the reference methods (manual) should be used. The diluted sample should be centrifuged, and the supernatant fluid measured with a spectrophotometer.
- Elevated lipemia: elevated lipemia levels makes the plasma look milky. This phenomenon can be seen with hyperlipidemia, hyperproteinemia (as in gammopathies) and hyperbilirubinemia.

Accurate hemoglobin measurement can be achieved by using reference (manual) methods and a plasma blank.

Increased turbidity: this phenomenon can be seen with red blood cells that are resistant to lysis. It causes a falsely elevated HGB concentration, but can be detected due to abnormal MCHC and MCH values and to an increase in the base line of the ascending section of the WBC curve. An erroneous hemoglobin concentration also causes erroneous MCH and MCHC values.

Fetal blood: the mixing of fetal and maternal bloods may produce a falsely elevated hemoglobin value.

6.3.4. Interferences on Hematocrit (HCT)

Red blood cells agglutination: can cause an inaccurate HCT value. Red blood cell agglutination may be detected by observing abnormal MCV and MCH values, and by examining a stained blood smear. In such cases, manual methods may be required to obtain an accurate hematocrit value.

6.3.5. Interferences on the Mean Cell Volume (MCV)

Red blood cell agglutination: can cause an inaccurate MCV value. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Excessive numbers of large platelets: and/or the presence of an excessively high WBC count may interfere with the accurate determination of the MCV value. In such cases, careful examination of a stained blood smear may reveal the error.

6.3.6. Interferences on the Mean Corpuscular Hemoglobin (MCH)

The interferences cited for HGB and RBC affect the MCH and may cause inaccurate results.

6.3.7. Interferences on the Mean Corpuscular Hemoglobin Concentration (MCHC)

The interferences cited for HGB and the HCT affect the MCHC and may cause inaccurate results.

6.3.8. Interferences on the Red Distribution Width (RDW)

The interferences cited for RBC and MCV affect the RDW and may cause inaccurate results.

Red blood cell agglutination: this phenomenon may cause a falsely low erythrocyte count and an erroneous RDW. In the blood samples, red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Nutritional deficiency or blood transfusion: these phenomena may cause elevated RDW results due to iron, vitamin B12, or folate deficiencies. It is also possible to observe an elevated RDW from the bimodal distribution of red blood cells from transfused blood.

6.3.9. Interferences on Platelets (PLT)

Very small erythrocytes (microcytes): the presence of erythrocyte fragments (schistocytes), and WBC fragments may interfere with the platelet count giving falsely elevated values.

Red blood cell agglutination: may trap the platelets and cause a falsely low platelet count. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Excessive numbers of giant platelets: this phenomenon may cause a falsely low platelet count due to the fact that these giant platelets exceed the upper threshold defined for platelets and are therefore not counted as platelets.

Chemotherapy: cytotoxins and immunosuppressants may weaken these cells and result in a falsely low count. Manual methods may be necessary to obtain the platelet count.

Hemolysis: hemolyzed samples contain a red blood cell stroma which may affect the platelet count.

Citrate blood - Blood anti-coagulated with citrate may contain platelet aggregates which could decrease the platelet count.

RBC Inclusions: including Howell-Jolly bodies, Heinz bodies, siderotic and basophilic granules, etc., may cause falsely elevated platelet counts.

Platelet agglutination: the accumulation of platelets may cause a low platelet count. The sample should be repeated and drawn into a sodium citrate anticoagulant tube to rule out the anticoagulant as a cause of aggregation and run again to determine the platelet count alone. The final platelet count should be corrected, making allowance for the dilution caused by the sodium citrate. Platelet agglutination triggers the alarms L1, LL, and LL1.

Elevated lipids and/or cholesterol: may interfere with correct platelet counting. From patients undergoing parenteral treatment with intralipids brought, it is noted an over-estimate of the platelet counting which can mask a thrombopenia in DIF mode. In this case, sample re-run should be done in CBC mode.

Elevated bilirubine: may interfere with correct platelet counting. From patients with severe hepatic disorder, liver transplant… It is noted an over-estimate of the platelet counting which can mask a thrombopenia.

Parenteral treatment: Interference in PLT result may occur for samples from patients undergoing parenteral treatment with injection of lipid emulsion.

6.3.10. Interferences on the Mean Platelet Volume (MPV)

Giant platelets: their volume exceeds the upper threshold defined for platelets and they are not therefore included in the calculation of the mean platelet volume by the analyzer. The MPV value may be falsely lowered.

Very small erythrocytes (microcytes): the presence of red blood cell fragments (schistocytes) and white blood cell fragments may interfere with the accurate determination of the mean platelet volume.

Red blood cell agglutination: may trap the platelets causing an incorrect MPV. Red blood cell agglutination may be detected by observing abnormal MCH and MCHC values, and by examining a stained blood smear.

Chemotherapy: may also affect platelet volume.

Blood samples collected in EDTA will not maintain a stable Mean Platelet Volume. Platelets collected in EDTA swell with time and temperature.

6.3.11. Interferences on Lymphocytes (LYM)

The presence of erythroblasts and erythrocytes that are resistant to lysis may cause an inaccurate lymphocyte count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of lymphocytes.

6.3.12. Interferences on Monocytes (MON)

The presence of large lymphocytes, atypical lymphocytes, lymphoblasts, and excessive numbers of basophils may cause an inaccurate monocyte count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of monocytes.

6.3.13. Interferences on Neutrophils (NEU)

The presence of excessive numbers of eosinophils, metamyelocytes, myelocytes, promyelocytes, blasts, and plasma cells, may cause an inaccurate neutrophil count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of neutrophils.

6.3.14. Interferences on Eosinophils (EOS)

The presence of abnormal granulations (degranulation of certain zones, toxic granulations, etc.) may interfere with the eosinophil count. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of eosinophils.

6.3.15. Interferences on Basophils (BAS)

The presence of significant numbers of white blood cells and / or large immature cells, as well as the contamination of the basophil counting channel may cause falsely high basophil counts. Limitations to the leukocyte count also apply to the determination of the number (absolute value) and percentage of basophils.

Over evaluation in the Basophil count

- Excessive number of leukocytes (leukocytosis) can cause artificial rise in the number of counted basophils due to the shifting of the leukocyte population in the zone of the basophil one.
- Monocytes and Blasts show large granules and may shift on the basophil counting area. This may interfere with an accurate count.
- An abnormally low number of leukocytes (leukopenia) may increase too the basophil results. The elements present in the zone of basophil are brought back on a small total quantity of leukocytes, which increases the statistical error and may cause variabilities in the percentage.
- The weakness of leukocyte cells shown in certain diseases (Chronic Lymphocytic Leukemia) or during anti-cancer treatment (chemotherapy) can be translated on the basophilic channel by under evaluation of the leukocytes because of their destruction and thus cause a statistical increase in the basophil ones.

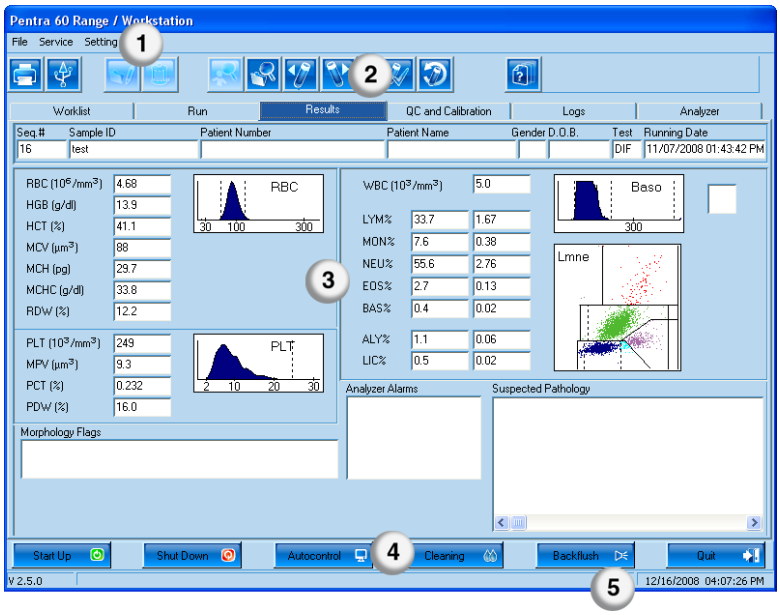
Under evaluation in the Basophil count

- During leukemia, basophils may lose their cytochemical characters and react abnormally with the reagent. The destruction of the basophil cytoplasms prevents their differentiation with the other leukocytes.
- The basophils with very small sizes (following treatments) may interfere with leukocyte counts, as cell sizes can not be distinguished.
- The abnormal basophils (degranulation following allergies) may interfere with leukocyte counts, because cell sizes can not be distinguished and because they may lose their characteristic intracytoplasmic material.

Software

1. Software Overview

A software application is installed on the Workstation which is connected to the Pentra ES 60.

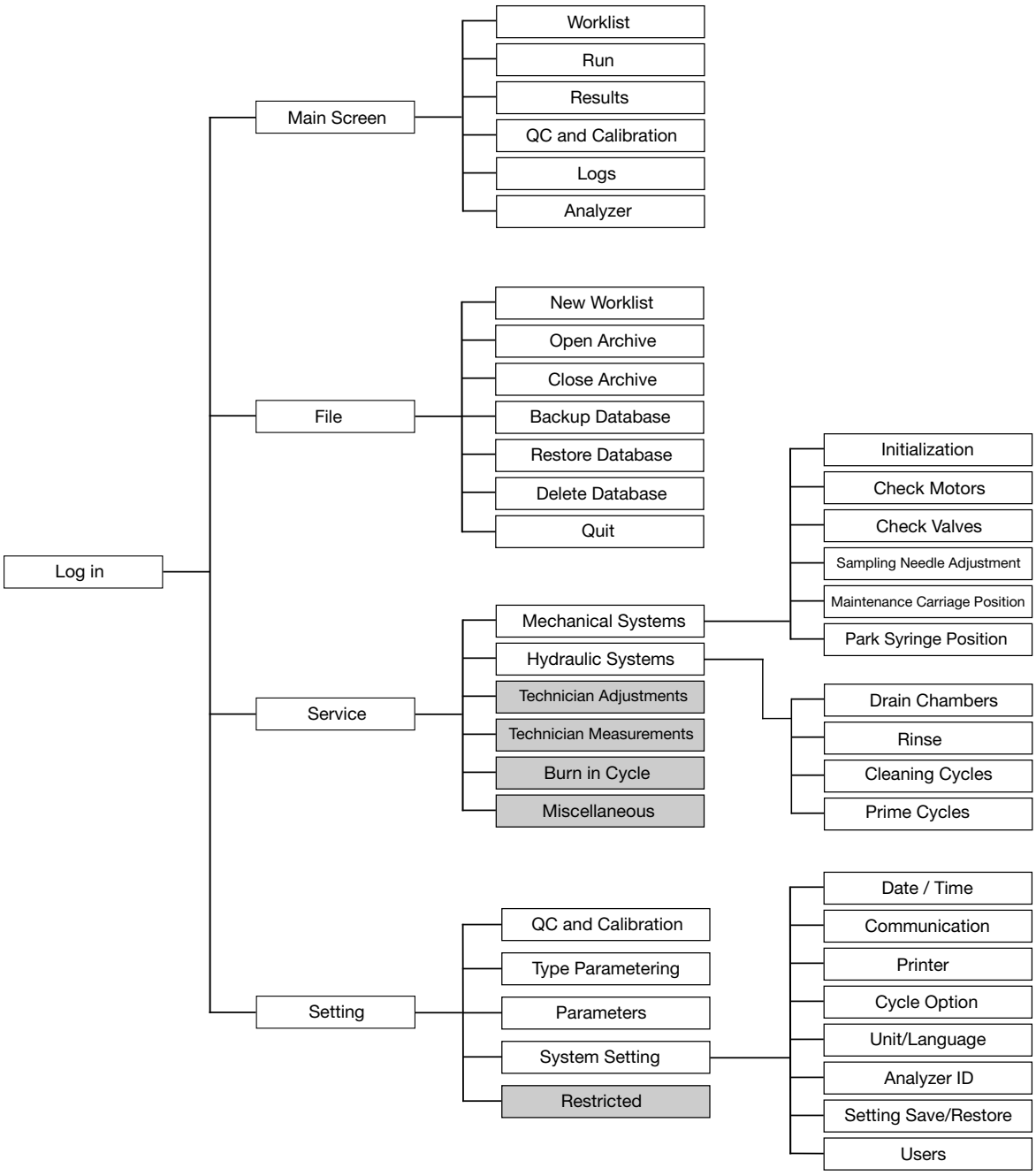


The Pentra ES 60 application includes the following items:

1. A **Menu Bar**, which allows you to navigate in menus described in the *Menus Description* chapter.
2. A **Toolbar**, with functions related to the displayed screen.
3. The **Content** area, depending on the selected menu item.
4. A **Cycle Toolbar** which allows you to launch cycles on the instrument and to quit the application.
5. A **Status Bar** which gives you information about the software version and the date / time.

See also:
- Software Functionalities, p.52
- Software Icons Description, p.50
- Menus Description, p.49

2. Menus Description



Menus displayed in grey are reserved to technicians and are protected by a password.

3. Software Icons Description

Print Selected Area: opens a dialog box to choose printing options.

Send Selected Areas: opens a dialog box to choose sending options.

Add New Entry: creates a new order file.

Delete: deletes selected data.

Display Search Screen: opens the search functionality.

Zoom/List: allows to switch from list screen to ***Order Entry*** screen (also accessible by double-clicking the entry).

Previous File: displays previous order in the list.

Next File: displays next order in the list.

Validate: validates result(s).

Rerun Sample: allows to program rerun of a non-validated order.

Screen Help: opens the instrument's user manual.

Start Cycle Startup: runs a startup.

Start Cycle Shutdown: runs a shutdown.

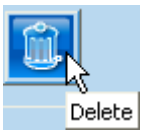
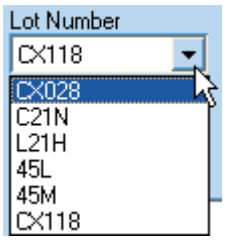
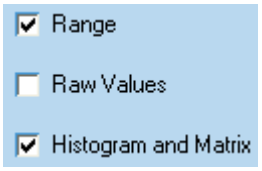
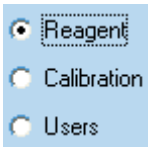
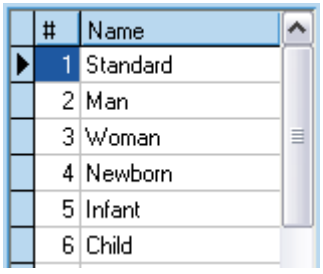
Start Cycle Autocontrol: runs an autocontrol.

Start Cycle Cleaning: runs a cleaning cycle.

Start Cycle Backflush: runs a backflush cycle.

Quit Instrument Application: closes the instrument application (confirmation needed).

4. Software Functionalities

Active icon	Icons are not always effective, depending on the screen currently displayed and instrument status. An active icon is darker.	
Deactivated icon	A deactivated icon is lighter.	
Tooltips	A tooltip is a short piece of information about an icon or an area. Place your mouse pointer over a key to display a tooltip.	
Dropdown lists	A drop-down list is a list of predefined items. Select one item from the list to select it. Only one item can be selected from the list.	
Check boxes	Check boxes are options you can select. Click the check box to select the option. Several options can be selected in a list of check boxes.	
Radio buttons	Radio buttons are options you can select. Click the radio button to select the option. Only one option can be selected in a list of radio buttons.	
Data fields	Data fields can have a predefined format, like a date field, or can be empty. Use the keyboard to enter data.	
Scroll bars	Scroll bars can be either vertical or horizontal. Use it to display hidden parts of the screen or a list.	

Calendars

Calendars help you to select a date. To choose a month, use the left and right arrows. Then choose the day. When done, click randomly outside the calendar to close it.

5. Worklist Keyboard Shortcuts

Keys combination	
Up arrow	goes to previous line
Ctrl + up arrow	goes to first line
Down arrow	goes to next line
Ctrl + down arrow	goes to last line
Previous page	goes to first line currently displayed / cancels lines current selection
Next page	goes to last line currently displayed / cancels lines current selection
Left arrow	moves to the left column
Ctrl + left arrow	moves to the first column on the left
Right arrow	moves to the right column
Ctrl + right arrow	moves to the first column on the right
Shift + down arrow	selects several items downwards
Shift + up arrow	selects several items upwards
Tab	moves to the next cell of the list
Shift + tab	moves to the previous cell of the list
Ctrl + delete	deletes the current selection
Escape	cancels non-saved modifications / cancels lines current selection

Key + Mouse combination	
Ctrl + click	selects a line
Ctrl + shift + click	selects a block of lines (only on entries already done)
Alt + click	switch to ***Results*** review (only on patients already done)
Double-click	switch to ***Order entry*** screen

Quality Assurance

1. Quality Control

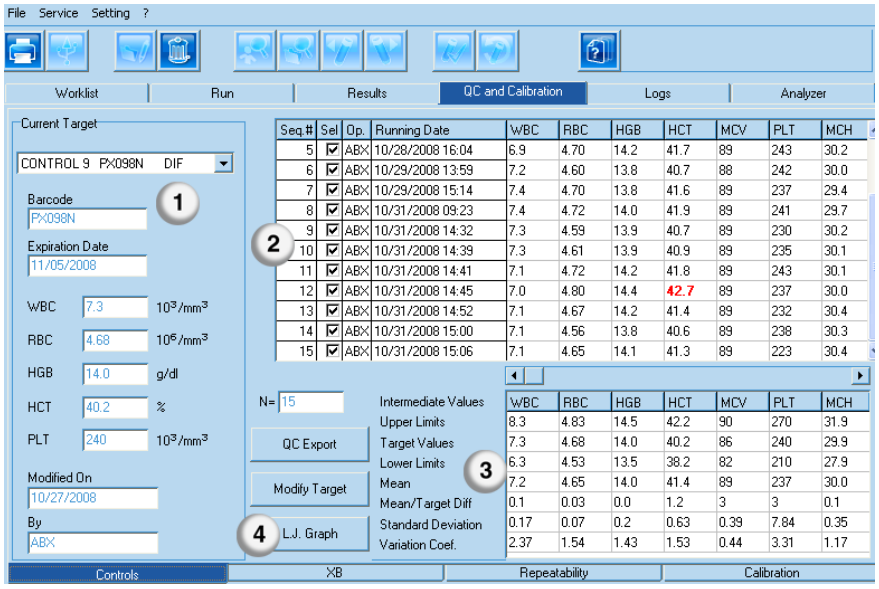
1.1. Quality Control Overview

*Access: **Main screen** > **QC and Calibration (tab)** > **Controls (tab)***

The Quality Control (QC) allows to monitor a set of analyses based on known sample values and ranges over a period of several months. Statistical computations performed on these populations allow the extraction of qualitative information, related to the stability of the instrument.

A maximum of twelve control lots can be created. To create a new control blood lot, you have to modify a control lot of the **Current Target** list. For each control lot, 400 results can be archived in the database.

Three control levels are available for each test (Low, Normal, High). The three controls can be simultaneously active allowing QC on three levels.



1 = Current target

This area provides information about the control lot selected in the QC lot numbers list. The lot number, barcode, expiration date and parameters values can be modified by clicking **Modify Target**.

If you replace or modify a lot, all previous data concerning this lot will be lost.

2 = Control's runs results

The results displayed in this area are those of the control lot selected in the QC lot numbers list. It is possible to select or unselect a result. For example, clear the first checkbox to discard the first result.

Results which are out of the limits defined in the ***Target Values*** window are blue (too low) or red (too high).

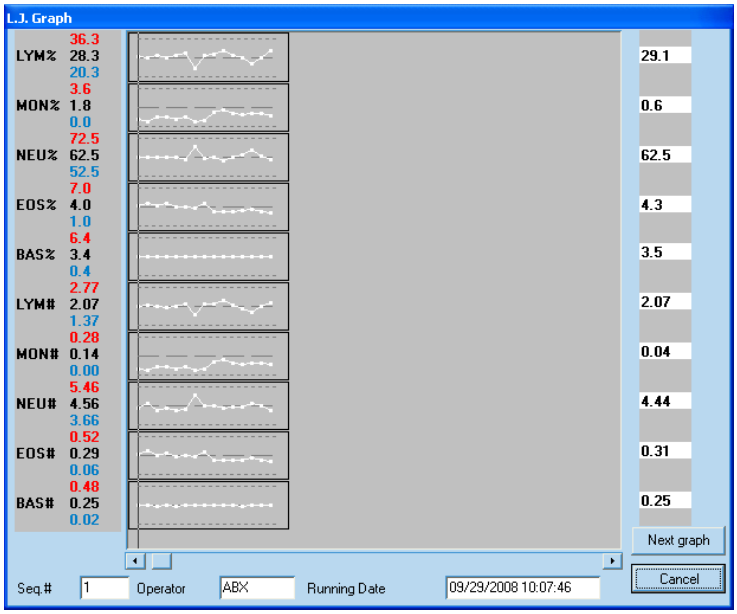
3 = Parameters statistics

This area provides statistics calculated from the selected results. If you select / unselect results, the statistics are automatically recalculated.

If a variation coefficient (in %) is out of the limits set by the user in ***Setting*** > ***QC and Calibration*** menu, the value's background turns to red.

4 = L.J. Graph

Levey Jennings (L.J.) graph is a graphical representation of quality control data. It is based on the daily value for each control parameter, its target value and range that are plotted on a graph for a periodic review.



For each parameter, a curve is displayed. A point on a curve represents a control blood analysis.

It is possible to move the marker (black vertical line) to switch from one analysis to another. This changes the number in the Seq.# field and the results on the right. To move the marker, you can either:

- click and drag
- use the horizontal scroll bar
- use the keyboard left and right arrows.

Each parameter has a normal value (in black), a high limit (in red) and a low limit (in blue). If a mean value of a result is higher or lower than the limit set up by the user, the points of the curve then turn to red or blue.

Click **Next Graph** to display more parameters.

See also:
- Worklist Overview, p.86
- QC and Calibration, p.124
- To Create / Modify a Control Lot, p.58
- To Export Quality Control Data, p.59
- To Identify a Control Blood with the Barcode Reader, p.80
- To Identify a Control Blood without Barcode Reader, p.81
- To Run a Control Blood, p.82
- To Check Control Blood Results, p.84

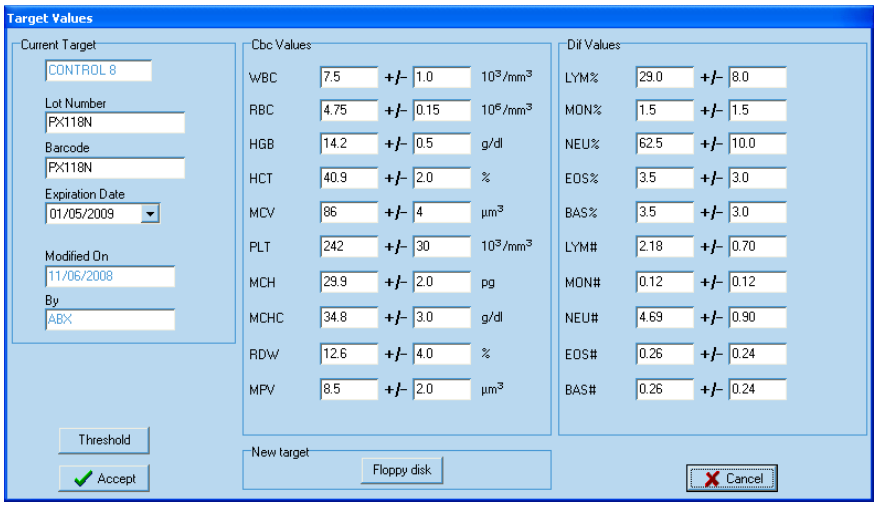
1.2. To Create / Modify a Control Lot

- Create a new control lot.
- Modify an existing control lot.

Access: ***Main screen*** > ***QC and Calibration (tab)*** > ***Controls (tab)***

The control lot you need is not in the ***Current Target*** *list, or the target values have to be modified.*

1. Select a control lot from the **Current Target** list.
2. Click **Modify Target**.
   The ***Target Values*** window is displayed:



The ***DIF Values*** area and the **Threshold** button are displayed only if the control lot is a DIF one. The threshold values are protected with a password.

3. Insert the floppy disk provided with the control specimen (if you do not have a floppy disk, enter manually the values for each parameter, the lot number, the barcode and the expiration date detailed in the control package insert).
The ***QC Target Level*** window is displayed:

If you replace or modify a lot, all previous data concerning this lot will be lost.

4. Choose the control blood level and click **OK** to validate.

The last letter of the lot number / barcode indicates the control level. Choose **Low** if it ends with an "L", **Medium** if it ends with an "N", or **High** if it ends with an "H".

5. In the ***Target Values*** window, click **Accept** to validate.

The control lot is modified.

See also:
- To Export Quality Control Data, p.59
- To Identify a Control Blood with the Barcode Reader, p.80
- To Identify a Control Blood without Barcode Reader, p.81
- To Run a Control Blood, p.82
- To Check Control Blood Results, p.84
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124

1.3. To Export Quality Control Data

Create a backup file with QC results and statistics on a floppy disk.

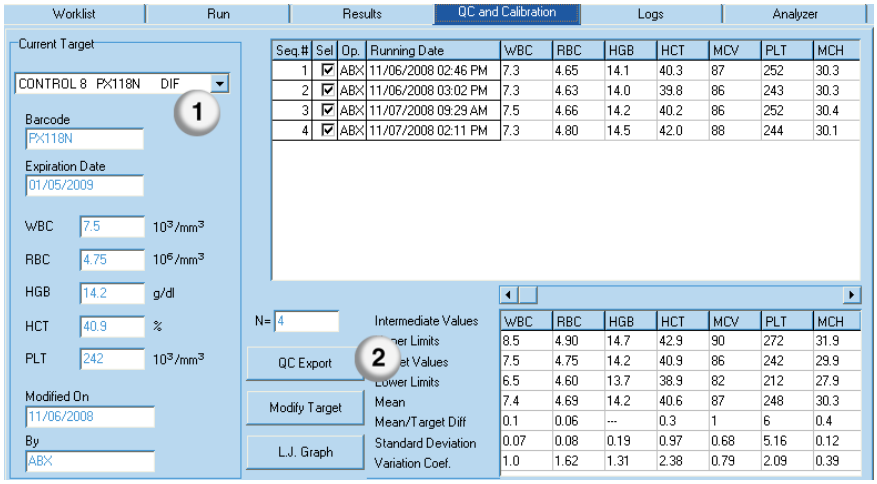
Access: ***Main screen*** > ***QC and Calibration (tab)*** > ***Controls (tab)*** > ***QC Export (button)***

At least one result must have been recorded.

The backup file created is a *.csv* file, readable with a spreadsheet program. One file is generated per control lot. The naming convention is the following : **xxx_YYYYMMDD.csv**, where xxx is the lot number and YYYYMMDD the file creation date.

RUO parameters (PCT, PDW, ALY, LIC) are not exported in the backup file.

1. Insert a formatted disk into the floppy drive.
2. In the ***Main screen*** > ***QC and Calibration (tab)*** > ***Controls (tab)*** , select the lot to export from the **Current Target** list (1).



3. Click **QC Export** (2).
4. Click **OK** to confirm QC export.

- This function copies following information to floppy disk:

  header : Instrument name / lab ID ; instrument serial number ; lot number ; file creation date time ; start period for lot use ; end period for lot use ; expiration date ; comment ; user lot comment ; unit used.
  CBC data (Minotrol) : 3 parts for Low, Normal and High levels ; results detailed by parameters ; statistics results ; lot target values
  DIF data (Difftrol) : 3 parts for Low, Normal and High levels ; results detailed by parameters ; statistics results ; lot target values
- Lot barcode identification must not be modified to allow QC export on the floppy disk.
- Statistical calculation results recorded in the file are based on the raw values determined by the instrument, and not by the rounded values of control runs displayed in this file.

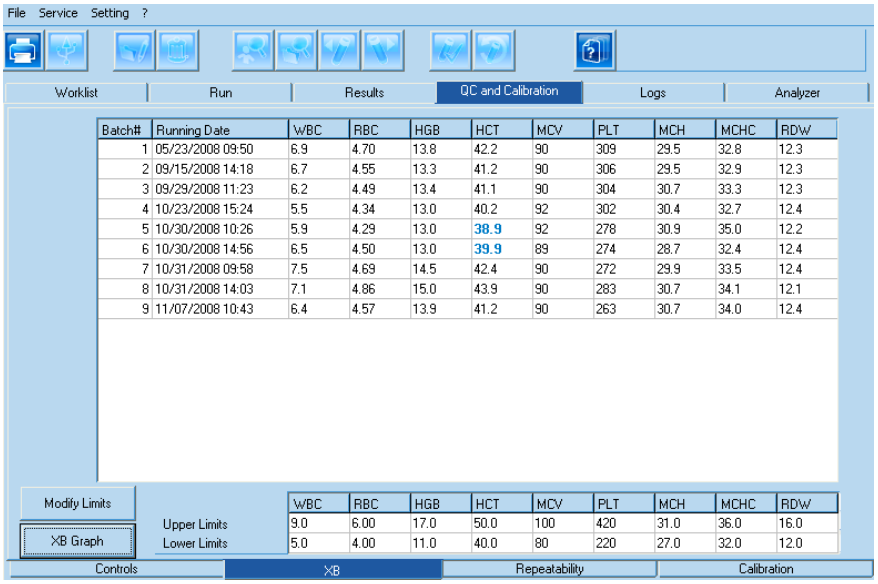
See also:
- To Create / Modify a Control Lot, p.58
- To Identify a Control Blood with the Barcode Reader, p.80
- To Identify a Control Blood without Barcode Reader, p.81
- To Run a Control Blood, p.82
- To Check Control Blood Results, p.84
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124

2. Patient Quality Control (XB)

2.1. Patient Quality Control (XB) Overview

*Access: **Main screen** > **QC and Calibration (tab)** > **XB (tab)***

The (XB) Patient Quality Control is used to detect any deviation in the quality of results, using patient data only. This data monitoring is based on a BULL method and can be applied to a set of 9 parameters (WBC, RBC, HGB, HCT, RDW, PLT, MCV, MCH, MCHC), or 3 parameters (MCV, MCH, and MCHC).



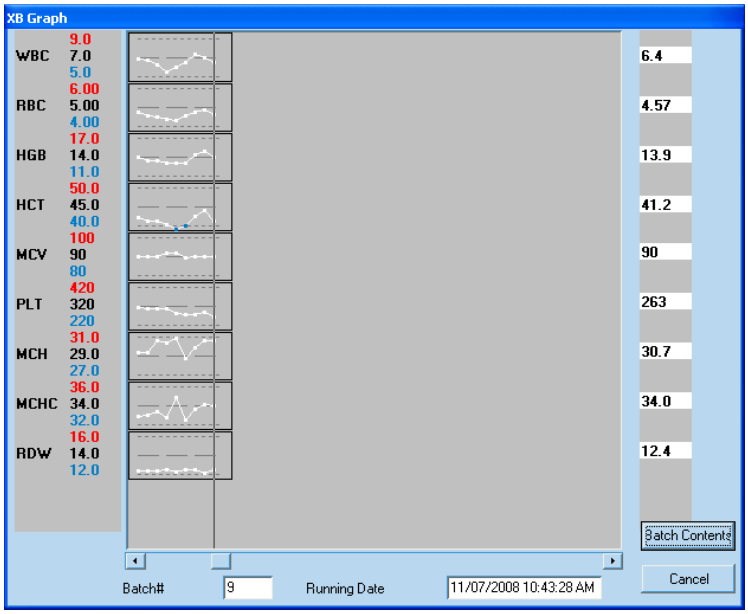
This quality control does not require any intervention from the operator, nor the running of any specific controls. The statistical calculation includes all patient results that does not contain analysis default. When 20 results have been archived, a batch is calculated. A batch is the mean result for 20 analyses contained in that specific batch.

The XB alarm occurs when the calculation of the last batch shows a point located outside of the limits set by the operator (displayed on the top-right hand-side of the XB main screen). This alarm can be disabled in ***Setting*** > ***QC and Calibration*** menu.

60 batches can be recorded. After 60 batches, each new batch overwrites the oldest one.

XB Graph

The ***XB Graph*** is a graphical representation of the XB batchs. Click **XB Graph** to display it:



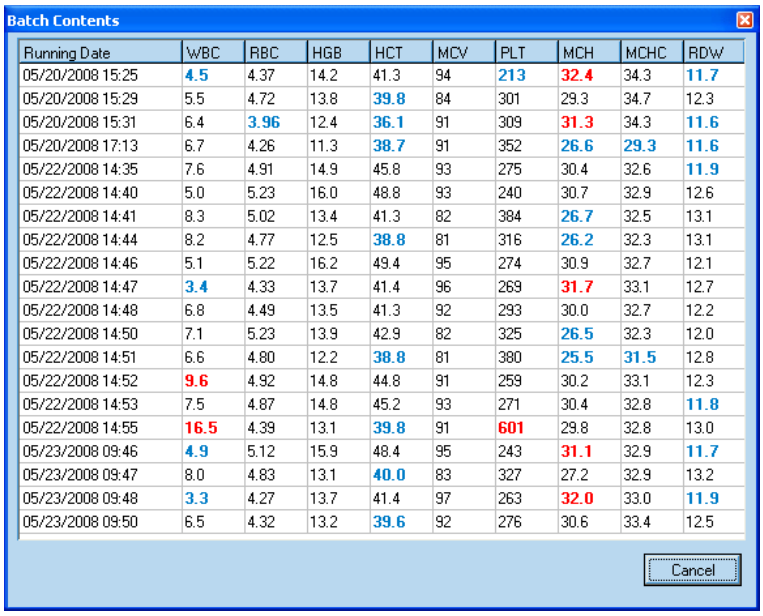
For each parameter, a curve is displayed. A point on a curve represents the mean value of the batch (20 runs). It is possible to move the marker (vertical line) to switch from one batch to another. This changes the batch number in the **Batch#** field and the batch results on the right. To move the marker, you can either:

- click and drag.
- use the keyboard left and right arrows.

Each parameter has a normal value (in black), a high limit (in red) and a low limit (in blue). If a mean value of a batch is higher or lower than the limit set up by the user, the points of the curve then turn to red or blue.

Batch Contents

The ***Batch Contents*** window gives the 20 results of the selected batch:



Running Date	WBC	RBC	HGB	HCT	MCV	PLT	MCH	MCHC	RDW
05/20/2008 15:25	4.5	4.37	14.2	41.3	94	213	32.4	34.3	11.7
05/20/2008 15:29	5.5	4.72	13.8	39.8	84	301	29.3	34.7	12.3
05/20/2008 15:31	6.4	3.96	12.4	36.1	91	309	31.3	34.3	11.6
05/20/2008 17:13	6.7	4.26	11.3	38.7	91	352	26.6	29.3	11.6
05/22/2008 14:35	7.6	4.91	14.9	45.8	93	275	30.4	32.6	11.9
05/22/2008 14:40	5.0	5.23	16.0	48.8	93	240	30.7	32.9	12.6
05/22/2008 14:41	8.3	5.02	13.4	41.3	82	384	26.7	32.5	13.1
05/22/2008 14:44	8.2	4.77	12.5	38.8	81	316	26.2	32.3	13.1
05/22/2008 14:46	5.1	5.22	16.2	49.4	95	274	30.9	32.7	12.1
05/22/2008 14:47	3.4	4.33	13.7	41.4	96	269	31.7	33.1	12.7
05/22/2008 14:48	6.8	4.49	13.5	41.3	92	293	30.0	32.7	12.2
05/22/2008 14:50	7.1	5.23	13.9	42.9	82	325	26.5	32.3	12.0
05/22/2008 14:51	6.6	4.80	12.2	38.8	81	380	25.5	31.5	12.8
05/22/2008 14:52	9.6	4.92	14.8	44.8	91	259	30.2	33.1	12.3
05/22/2008 14:53	7.5	4.87	14.8	45.2	93	271	30.4	32.8	11.8
05/22/2008 14:55	16.5	4.39	13.1	39.8	91	601	29.8	32.8	13.0
05/23/2008 09:46	4.9	5.12	15.9	48.4	95	243	31.1	32.9	11.7
05/23/2008 09:47	8.0	4.83	13.1	40.0	83	327	27.2	32.9	13.2
05/23/2008 09:48	3.3	4.27	13.7	41.4	97	263	32.0	33.0	11.9
05/23/2008 09:50	6.5	4.32	13.2	39.6	92	276	30.6	33.4	12.5

To open the ***Batch Contents*** window:

- Click **Batch Contents** in the ***XB Graph*** window, or

- Doucle-click on a batch row in the XB main screen.

See also:
- QC and Calibration, p.124
- XB Limits, p.152
- To Modify XB Limits, p.63

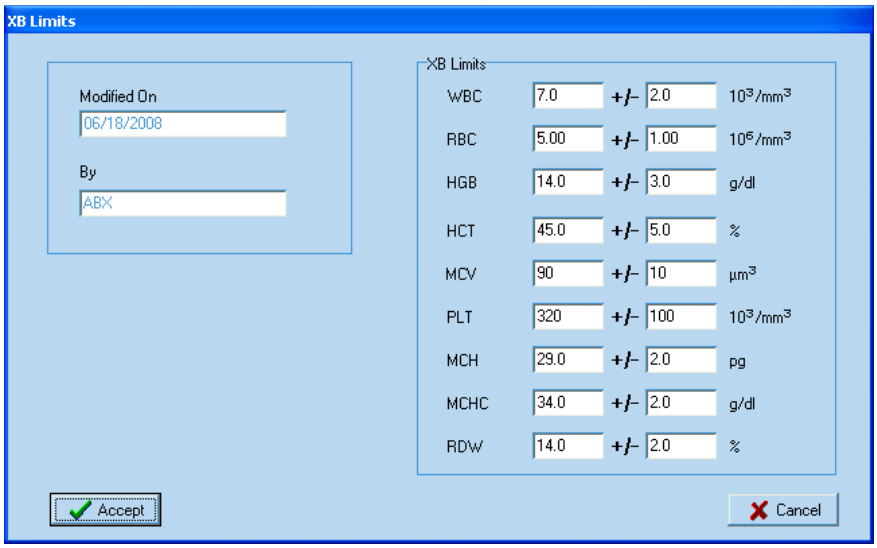
2.2. To Modify XB Limits

Modify the XB values and the permissible margin for each parameter.

*Access: **Main screen** > **QC and Calibration (tab)** > **XB (tab)***

The XB main screen must be displayed.

1. Click **Modify Limits**.
   The ***XB Limits*** window is displayed:



2. Change the values and the permissible margin of the parameters you want to modify.
3. Click **Accept** to validate.

See also:
- Patient Quality Control (XB) Overview, p.61
- QC and Calibration, p.124
- XB Limits, p.152

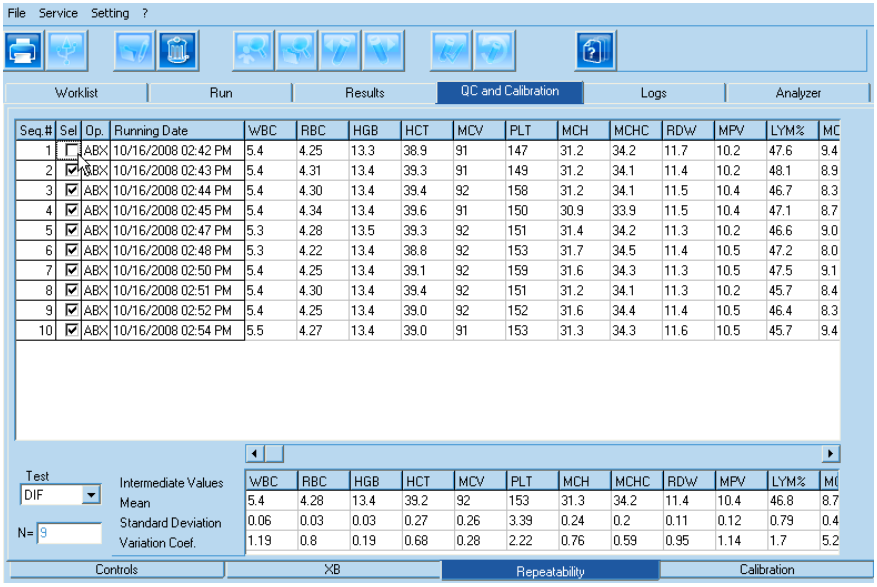
3. Repeatability

3.1. Repeatability Overview

*Access: **Main screen** > **QC and Calibration (tab)** > **Repeatability (tab)***

The measurement of repeatability is based on a set of results obtained from consecutive analyses of the same human fresh normal blood sample.

At first, the message "*Results Will Be Erased, Please Confirm*" is displayed. If you click **OK**, the current list is deleted. If you want to keep it, click **Cancel**.



CBC or DIF tests can be done (combination is not supported) with a limit of 35 results per test. Beyond the 35th result, data generated from a new analysis are disregarded.

Results are listed in the first table and statistical calculations are performed in the second one.

If a variation coefficient (in %) is out of the limits set by the user in ***Setting*** > ***QC and Calibration*** menu, the value's background turns to red.

To get a proper CV calculation, the results containing defaults generated directly from the analyses channels are rejected. In that case, the message "*Rejected result not recorded*" is displayed.

In the first table, each line provides the following information:

- Sample number
- Name of operator
- Running date and time
- Value for each parameter

These results can be printed and/or deleted.

See also:
- Precision Claims, p.31
- To Perform a Repeatability, p.65

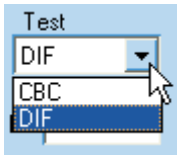
3.2. To Perform a Repeatability

Check the repeatability of your instrument.

Access: ***Main screen*** > ***QC and Calibration (tab)*** > ***Repeatability (tab)***

A fresh normal human blood is needed.

1. Select the type of test on which you want to do a repeatability: **CBC** or **DIF**.



2. Run the blood sample.
   The results are archived in the list.
3. Wait until LED is green for next run.
4. Repeat steps 2 and 3 between five and ten times with the same blood sample.
5. Check the values calculated to know whether or not repeatability is good.

See also:
- Repeatability Overview, p.64
- Precision Claims, p.31

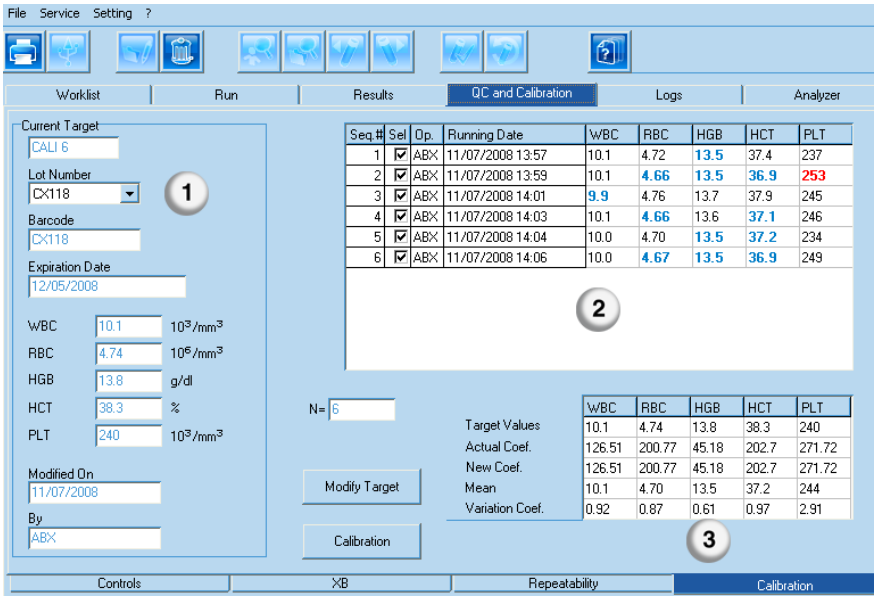
4. Calibration

4.1. Calibration Overview

Access: ***Main screen*** > ***QC and Calibration (tab)*** > ***Calibration (tab)***

At first, the message "*Results Will Be Erased, Please Confirm*" is displayed. If you click **OK**, the current list is deleted. If you want to keep it, click **Cancel**.

The calibration function is used to determine the precision and accuracy of the analyzer, with use of a specifically formulated product, to recover each parameter within close tolerances of known target values and limits. Coefficients of variation and percent difference recovery must be within their specified limits.



1 = Current target

This area provides information about the calibrator lot selected in the **Lot Number** list. The lot number, barcode, expiration date and parameters values can be modified by clicking **Modify Target**.

If you replace or modify a lot, all previous data concerning this lot will be lost.

2 = Calibrator's runs results

The results displayed in this area are those of the calibrator lot selected in the **Lot Number** list. It is possible to select or unselect a result. For example, clear the first check box to discard the first result.

Results which are out of the limits defined in the ***Target Values*** window are blue (too low) or red (too high).

3 = Parameters statistics

This area provides statistics calculated from the selected results. If you select / unselect results, the statistics are automatically recalculated.

If a variation coefficient (in %) is out of the limits set by the user in ***Setting*** > ***QC and Calibration*** menu, the value's background turns to red.

Make sure coefficients are within limits detailed in *Settings* > *Instrument Default Settings* chapter. If not, please contact your local HORIBA Medical representative.

See also:
- General Recommendations, p.67
- QC and Calibration, p.124
- To Calibrate the Instrument, p.68
- To Create / Modify a Calibrator Lot, p.70
- Calibration Coefficients, p.

4.2. General Recommendations

Perform these preliminary actions before calibrating the instrument.

- The calibration is an exceptional procedure which must be carried out, particularly after certain technical interventions (installation, maintenance, service intervention).
- The calibration should not be carried out to compensate a drift on a result due, for example, to clogging of the instrument.
- If the frequency of re-calibration is too important, it may be the sign of the beginning of a problem (technical, reagents, etc.)

Make sure that the instrument is in perfect operating condition:

1. Run a startup cycle. The startup must be successful to start calibration. See *Workflow* > *Start of Day* chapter.
2. Perform a concentrated cleaning procedure. See *Maintenance and Troubleshooting* > *Maintenance* chapter.
3. Perform two blank cycles to check the cleanliness of the instrument.
4. Check the repeatability of the instrument by running a fresh human normal blood sample 11 times with no alarm. Discard the first result and calculate the CV on the remaining 10 runs. See *QC and Calibration* > *Repeatability* chapter.

5. Check that the CV calculated using the remaining 10 runs meets or exceeds the specifications. See *Specifications* > *Summary of Performance Data* chapter.
6. Run a control blood and check that the values are within acceptable limits. If not, run a new control blood. See *Workflow* > *Running Quality Control Blood* chapter.
7. If the startup passed, if instrument is clean (blank cycles in conformity with the target values), if repeatability is correct, and the values are still out of the acceptable limits, then carry out a calibration.

See also:
- Precision Claims, p.31
- To Perform a Manual Startup, p.78
- To Perform a Concentrated Cleaning, p.167
- To Perform a Repeatability, p.65
- To Run a Control Blood, p.82
- Calibration Overview, p.66
- QC and Calibration, p.124
- To Calibrate the Instrument, p.68
- To Create / Modify a Calibrator Lot, p.70

4.3. To Calibrate the Instrument

Perform a calibration of your instrument.

Access: ***Main screen*** > ***QC and Calibration (tab)*** > ***Calibration (tab)***

You must have performed the tasks described in Calibration > General Recommendations chapter.

To calibrate the instrument, use the ABX Minocal calibrator.

1. Select the calibrator from the **Lot Number** list.
   If the calibrator is not listed, see *To Create / Modify a Calibrator Lot* chapter.
2. Prepare the calibrator according to the specific instructions detailed in the calibrator package insert (temperature, mixing, etc.).
3. Run the calibrator. The instrument LED has to be green.

Always wipe any excess blood from the cap and threads of the calibrator vial with a lint-free tissue to prevent dried blood from re-entering into the calibrator material. Dried blood re-entering into the vial may cause erroneous results such as flags and sample runs rejects.

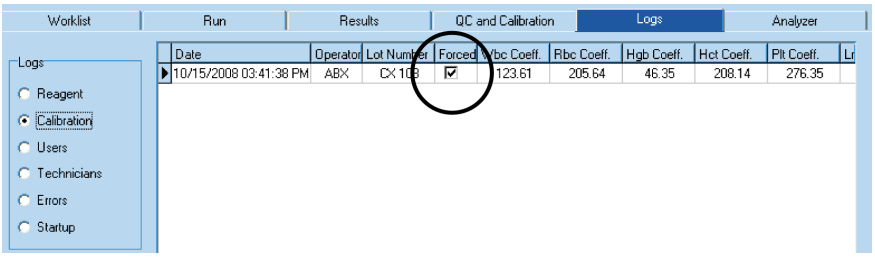
Risk of erroneous results if the specimen is not continously mixed between each analysis. Keep on mixing the specimen between each analysis.

4. Repeat step 3 at least four times.

In order to get a reliable calibration, it is recommended to run at least four calibrator samplings, and to discard the first one. 3 to 11 samplings can be done for a calibration.

5. Discard the first result from the list.
   The instrument calculates the statistical calibration factors for each parameter.

6. If the coefficient of variation is within the limits (+/- 20%), calibration is possible: click **Calibrate** to update calibration coefficients.
   If the coefficient of variation is out of limits, calibration is still possible, but is "**Forced**", as indicated in the calibration log:



7. Click **OK** to confirm calibration.
   Calibration log is updated.

8. Run three times the same calibrator to check the values.
9. Run a control blood and check that the values are within acceptable limits. If not, run a new control blood.
   See *Workflow* > *Running Quality Control Blood* chapter.

10. After about thirty analyses, check values of MCV, MCH and MCHC.
    They have to be in conformity with the usual values of the laboratory.

See also:
- To Create / Modify a Calibrator Lot, p.70
- Calibration Overview, p.66
- General Recommendations, p.67
- QC and Calibration, p.124
- Running Quality Control Blood, p.80

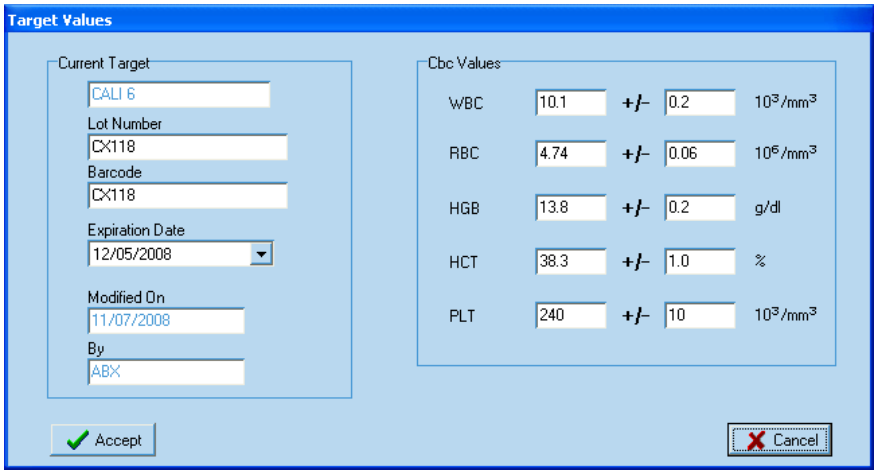
4.4. To Create / Modify a Calibrator Lot

- Create a new calibrator lot.
- Modify an existing calibrator lot.

*Access: **Main screen** > **QC and Calibration (tab)** > **Calibration (tab)***

*The calibrator lot you need is not in the **Lot Number** list, or the target values have to be modified.*

1. Select a calibrator from the **Lot Number** list.
2. Click **Modify Target**.
   The ***Target Values*** window is displayed:



3. Enter the values for each parameter and the expiration date detailed in the calibrator package insert.

If you replace or modify a lot, all previous data concerning this lot will be lost.

4. Click **Accept** to validate.

The calibrator lot is modified.

See also:
- To Calibrate the Instrument, p.68
- Calibration Overview, p.66
- General Recommendations, p.67
- QC and Calibration, p.124

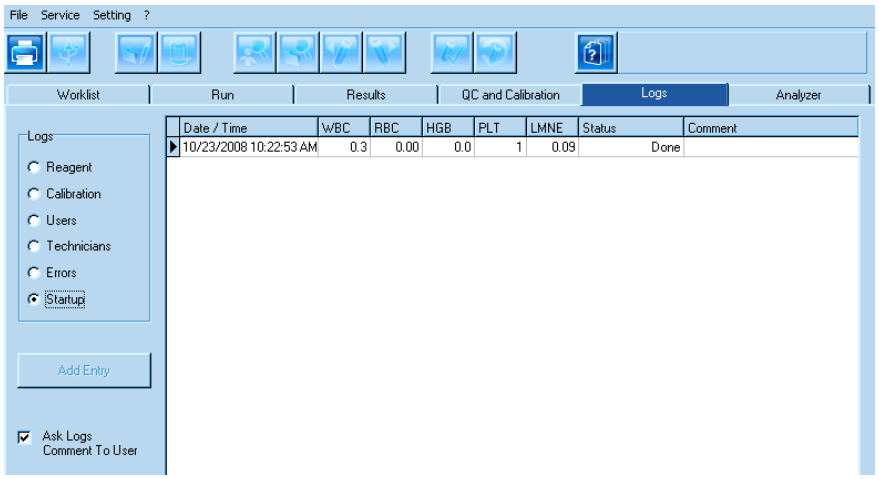
5. Logs

5.1. Logs Overview

*Access: **Main screen** > **Logs (tab)***

The logs list events of your instrument for the following:

- **Reagent**: information about a reagent replacement
- **Calibration**: information about the parameters coefficients
- **Users**: comments after a maintenance for users
- **Technicians**: comments after a maintenance for technicians
- **Errors**: description of system errors
- **Startup**: instrument startup results



Ask Logs Comment To User option: if selected, a comment dialog box is displayed after having performed the following:

- Reagent replacement
- Calibration
- Cytometer rinse
- Concentrating cleaning
- Blank cycle
- System error

5.2. To Add a New Entry

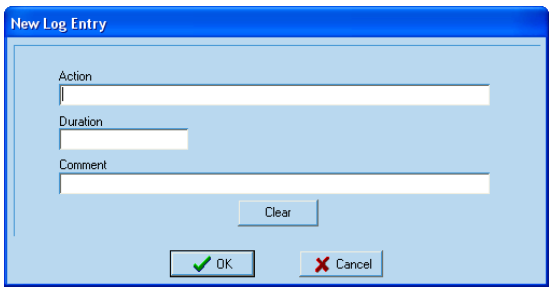
Add a new log entry after a maintenance.

*Access: **Main screen** > **Logs (tab)***

*Adding a new entry can only be done in **Users** and **Technicians** logs (this latter is protected by a password).*

After any maintenance operation done by a user or a HORIBA Medical technician, add a new log entry to keep the information archived.

1. Click **Add Entry** in the **Users** Log.
   The ***New Log Entry*** window is displayed:



2. If the fields are not empty, click **Clear** to empty them.
3. Enter the action performed, its duration and a comment.
4. Click **OK** to validate.

Workflow

1. Start of Day

1.1. To Check the Waste Container Level

1. Check the level of waste in the container.
2. If it needs to be emptied, refer to the *Maintenance and Troubleshooting* > *Maintenance* > *To Replace the Waste Container* chapter.

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubes and the liquid waste tube under any condition.

Waste must be handled according to your local and/or national regulations.

See also:
- To Replace the Waste Container, p.164
- Waste Handling Precautions, p.40

1.2. To Switch On the Printer

Start the printer at the beginning of the day.

Check if the printer has enough paper for daily operations. If not, add some paper following the instructions of the printer's user guide.

1. Press the **ON/OFF** switch.
2. Wait during printer's initialization.

3. Check that the control LEDs are on.

If the printer does not work properly, refer to its user guide.

See also:
- Printer Operation Problems, p.178
- Printer, p.22

1.3. Starting the Instrument

1.3.1. To Switch On the Instrument

Switch on the instrument and workstation at the beginning of your work session.

Before switching on the instrument and workstation, check the following:

- Check operational conditions described in *Introduction* > *Operational Conditions* chapter.
- Check all instrument and workstation connections. To know more about connections, see *Introduction* > *Label and Connections* chapter.
- Check if the waste container needs to be emptied. Follow instructions in *Specifications* > *Reagent Specifications* > *Waste Handling Precautions* chapter.

1. Switch the workstation on.
2. Switch the instrument on.
3. Wait during initialization.
   The ***Login*** window is displayed.
4. Log in as «abx» (no password required). Press **Enter** key to validate.

The ***Pentra 60 Range / Workstation*** login window is displayed.

You can now log in the application.

See also:
- Operational Conditions, p.14
- Waste Handling Precautions, p.40
- Computer Connections, p.21
- Diluent and Waste Connections, p.19
- Peripherals Connections, p.20

1.3.2. To Log in the Application

Log in the application with your user name and password.

- *The login window must be displayed.*
- *Your «user» profile must have been priorly created.*

To enter the application, each user must be logged in, with its own username and an associated password: refer to *Settings* > *Users* chapter.

1. Select a username from the **Operator** drop-down list.
2. Type in your password in the **Password** field.
3. Click **OK**.

If an error message is displayed during initialization or if the application does not start properly, please contact your local HORIBA Medical representative.

Once logged in, the main screen is displayed. For more information, see Software > Software Overview chapter.

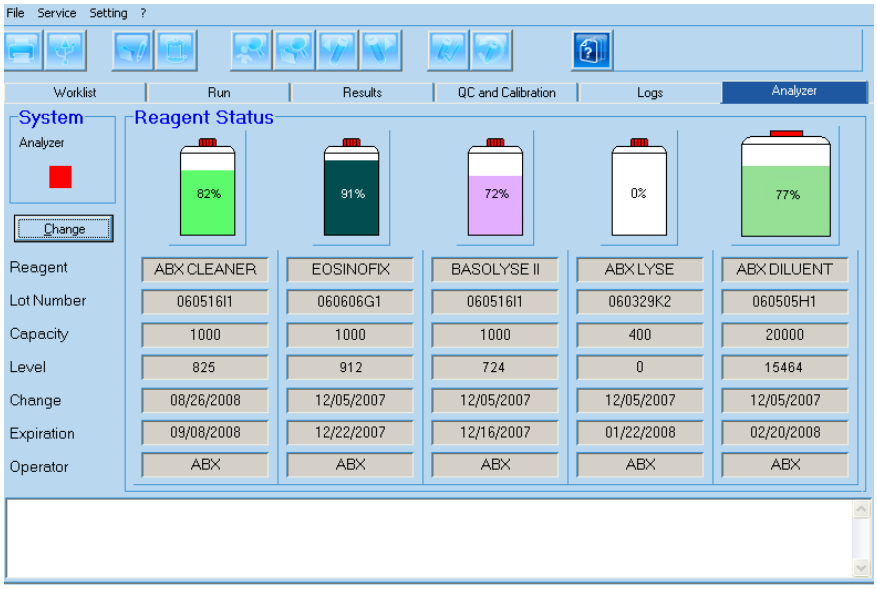
See also:
- Software Overview, p.48
- Users, p.138
- To Change Operator, p.120

1.3.3. To Control the Reagents

Check each reagent's level and expiration date before running a startup cycle.

*Access: **Main screen** > **Analyzer (tab)***

1. Check the level of each reagent. The percentage indicates the remaining level:



If one reagent has to be changed, refer to the *Maintenance and Troubleshooting* > *Maintenance* > *Reagents Replacement* chapter.

Verification after a reagent replacement: make sure a blank cycle and a control run have been performed after a reagent replacement during the day.

2. Check the expiration date of each reagent in the **Expiration** fields.

See also:
- To Replace a Reagent Bottle, p.161
- To Replace the Diluent Container, p.159
- To Replace the Waste Container, p.164
- To Prime Reagents, p.163

1.3.4. Instrument Startup

Startup is used to control the analyzer before running analysis. It can be launched manually, or automatically depending on the application settings.

1.3.4.1. To Perform a Manual Startup

*Access: **Main screen** > **Start Up (icon)***

- *The **Cycle Option** that enables the automatic startup is not checked (see Settings > System Settings chapter).*
- *The **System** analyzer indicator (see **Analyzer** tab) has turned to green.*

1. Click **Start Up**:

A progression bar is displayed. Wait until it stops before doing any other action.

2. Wait during startup cycle.
   Background counts (analysis cycle on reagent without blood specimen) are performed during startup cycle. The startup is passed if background counts are within acceptable limits:

Parameters	Background count limits
WBC	0.3 x 10^3/mm^3
RBC	0.03 x 10^6/mm^3
HGB	0.3 g/dL
PLT	7 x 10^3/mm^3

   Once startup is done, a ***Logs Comment*** window is displayed.

3. Enter a comment in the **Comment** field and click **OK** to validate.
   Results of the startup are saved and can be consulted in the logs. To know more about *Blank log*, see *Quality Assurance* > *Logs* chapter.

If the startup passes, the instrument is ready for control blood analysis.

If the startup fails, the instrument can run analyses but a "Startup Failed" message is displayed on next cycles. See Maintenance and Troubleshooting > Troubleshooting Procedures > Operation Problems > Startup Failed chapter.

It is mandatory to power down the system if not used for more than a 36 hour period. This eliminates the possibility of the dilution chambers evaporating and causing startup problems.

See also:
- To Run the Specimen, p.94
- To Perform a Concentrated Cleaning, p.167
- Logs Overview, p.71
- Cycle Option, p.135
- Startup Failed, p.179

1.3.4.2. To Schedule an Automatic Startup

Access: ***Setting*** > ***System Settings*** > ***Cycle Option (tab)***

If the ***Automatic Startup*** has been scheduled, it is run as soon as connections with instrument have been checked, as well as reagents levels.

1. Select the **Enable Automatic Startup** option.
2. Restart both instrument and workstation to get an automatic startup.

Once startup is done, results are available in ***Logs*** > ***Blank Log*** menu. To know more about **Blank Log** menu, see *Quality Assurance* > *Logs* chapter.

If the startup passes, the analyzer is ready for analysis.

If the startup fails, the analyzer is ready for analysis but a "Startup Failed" message is displayed on next cycles.

See also:
- Cycle Option, p.135

2. Running Quality Control Blood

2.1. To Identify a Control Blood with the Barcode Reader

Access: ***Main screen*** *>* ***Worklist (tab)***

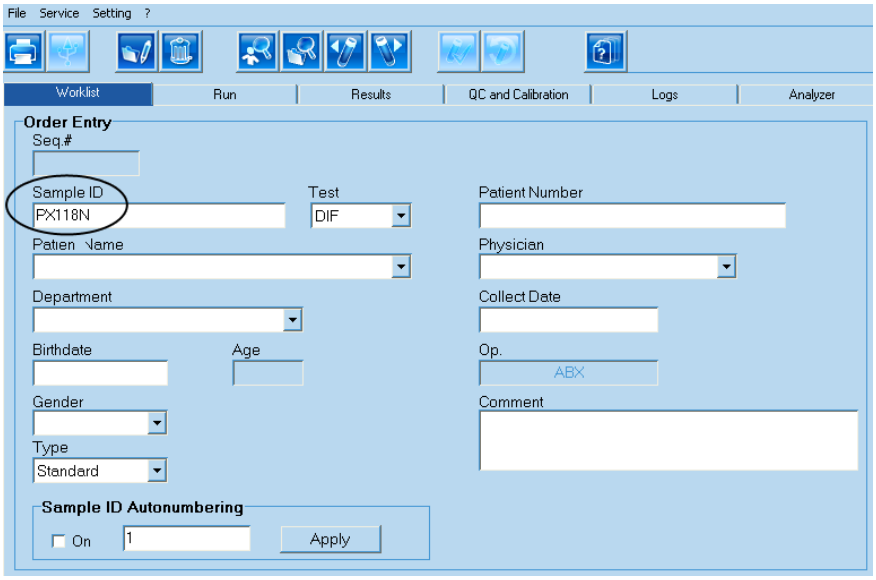
- *The instrument has to be ready for analysis.*
- *The control specimen must be identified with a barcode label.*
- *The lot number and target values have been previously defined.*

Make sure your control lot has been checked in the ***Reserved Barcode Choice*** *list of the* ***Setting*** *>* ***QC and Calibration*** *menu.*

To know more about control blood lot initialization, see the *Quality Assurance* > *Quality Control* chapter.

ABX Difftrol : this control material is specifically designed for use on Pentra ES 60, which includes a complete blood count and a 5-part WBC differential (CBC & DIF).

1. Click **Add New Entry**.
2. Read the sample's barcode label with the barcode reader.
   The lot number is displayed in the **Sample ID** field.



3. Click the ***Run*** tab.
   The control lot number is displayed.

The instrument is ready to run your control blood.

See also:
- To Create / Modify a Control Lot, p.58
- To Export Quality Control Data, p.59
- To Identify a Control Blood without Barcode Reader, p.81
- To Run a Control Blood, p.82
- To Check Control Blood Results, p.84
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124

2.2. To Identify a Control Blood without Barcode Reader

Identify your control blood lot if there is no barcode label.

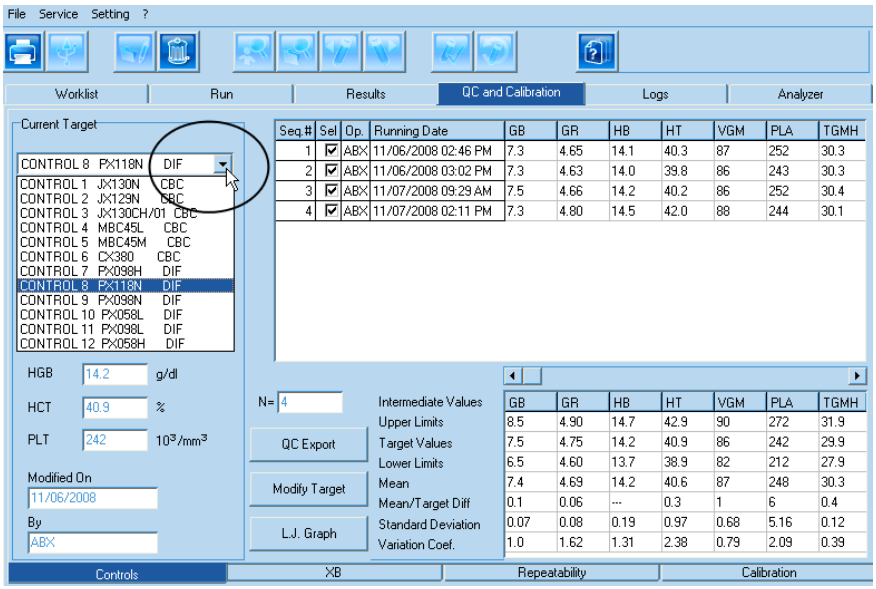
*Access: **Main screen** > **QC and Calibration (tab)** > **Controls (tab)***

- *The instrument has to be ready for analysis.*
- *The lot number and target values have been previously defined.*

To know more about control blood lot initialization, see Quality Assurance > Quality Control chapter.

ABX Difftrol : this control material is specifically designed for use on Pentra ES 60, which includes a complete Blood Count and 5-part White blood cell differential (CBC & DIF).

1. Open the **Controls** tab.



2. In the ***Current Target*** drop-down list, select your control lot.
   If your control blood is not listed, please refer to *Quality Assurance* > *Quality Control* chapter.

The instrument is ready to run your control blood.

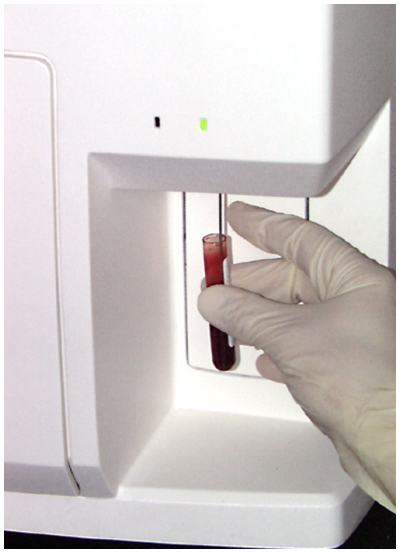
See also:
- To Create / Modify a Control Lot, p.58
- To Export Quality Control Data, p.59
- To Identify a Control Blood with the Barcode Reader, p.80
- To Run a Control Blood, p.82
- To Check Control Blood Results, p.84
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124

2.3. To Run a Control Blood

Prepare the control blood and run an analysis.

The control blood has previously been identified and the front panel LED has to be green.

1. Prepare your control blood according to the specific instructions detailed in the control blood package insert (temperature, mixing, etc.)
2. Plunge the sampling needle into the control blood specimen and press the start bar.



3. Remove the tube when the light indicator stops flashing.
   The LED turns to red.
4. Recap the control blood specimen.
5. If you want to rerun once again your control blood, you can:
   a. Proceed to your control blood tube identification.
   b. Rerun it as described in step 2.

Risk of erroneous results if the specimen is not continously mixed between each analysis.
Keep on mixing the specimen between each analysis.

See also:
- To Create / Modify a Control Lot, p.58
- To Export Quality Control Data, p.59
- To Identify a Control Blood with the Barcode Reader, p.80
- To Identify a Control Blood without Barcode Reader, p.81
- To Check Control Blood Results, p.84
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124

2.4. To Check Control Blood Results

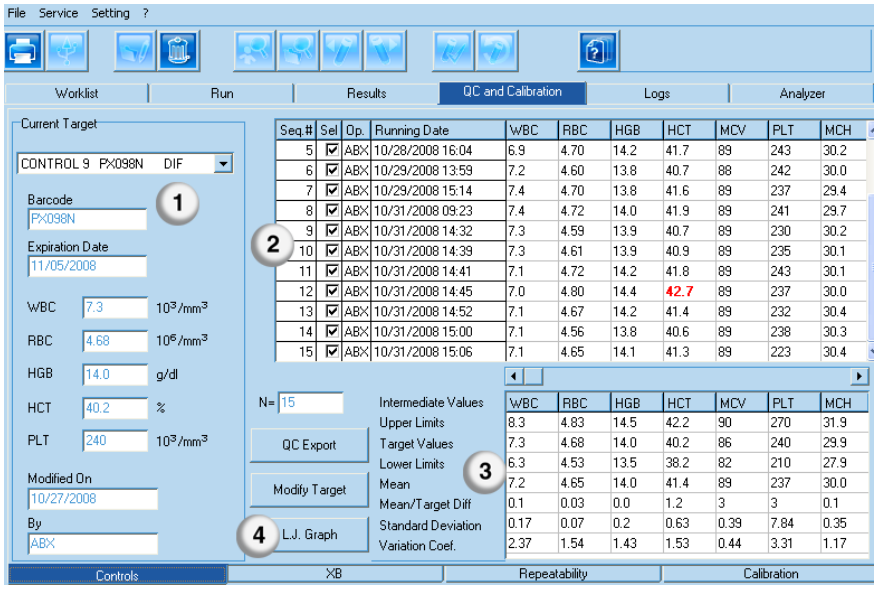
Check that control blood results are within the acceptable values.

*Access: **Main screen** > **QC and Calibration (tab)** > **Controls (tab)***

A control blood specimen must have been run.

1. Check your control blood results.
   As runs are sorted by date, your last run is the last line of table **2**.

2. Check that the results are within acceptable values given in the control blood leaflet.



   When control results are not within the acceptable values, the parameter results are displayed:
   - in red color if the values are too high,
   - in blue color if the values are too low.

   If any parameter results (**2**) and/or any statistical data (**3**) are out of ranges, perform the following:

3. Verify that the analyzed control blood results correlates with control lot (**1**). If not, perform a control identification procedure.
4. Rerun the control blood.
5. If results still do not match, perform a concentrated cleaning, and rerun the control blood again.
   See *Maintenance & Troubleshooting > To Perform a Concentrated Cleaning* chapter.

If results still do not match, you may need to re-calibrate your instrument. See Quality Assurance > Calibration chapter before attempting any calibration operation.

See also:
- To Create / Modify a Control Lot, p.58
- To Export Quality Control Data, p.59
- To Identify a Control Blood with the Barcode Reader, p.80
- To Identify a Control Blood without Barcode Reader, p.81
- To Run a Control Blood, p.82
- Quality Control Overview, p.56
- Worklist Overview, p.86
- QC and Calibration, p.124
- To Perform a Concentrated Cleaning, p.167
- Calibration Overview, p.66

3. Worklist

3.1. Worklist Overview

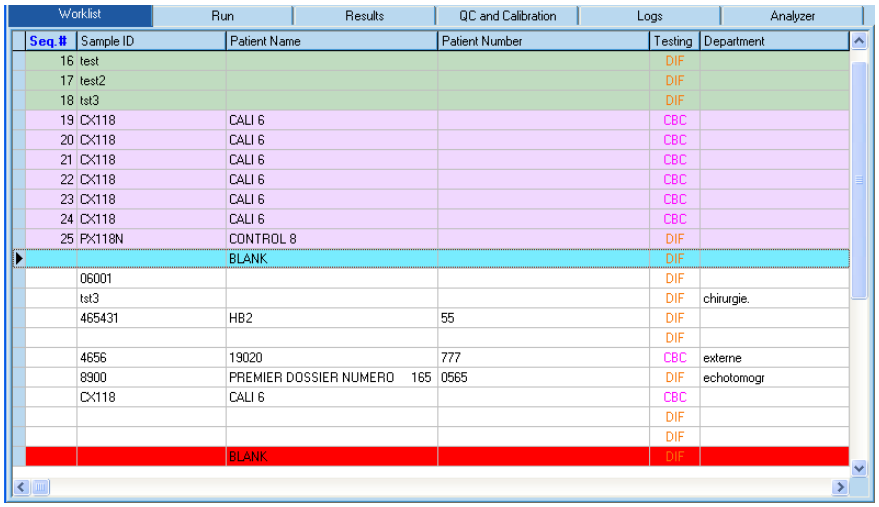
*Access: **Main screen** > **Worklist (tab)***

The worklist provides the list of orders to perform, those currently in analysis and those already run. New orders can be created from this menu. These ones include all the patient data and the test to carry out.

Worklist screen description

Two views are available:

- one is a list with one analysis by line.
- one is a detailed view of each field of the patient: ***Order Entry*** (refer to *Worklist > To create a new Worklist* chapter).



Worklist Fields

Seq. # The sequence number is automatically incremented by the software and is unique.

Sample ID When you enter the ***Sample ID***, it is compared to the list of reserved numbers corresponding to Control, Calibration or Repeatability analyses. If its ID already exists, the entry is automatically completed.
If it has not been found, it is searched among already run patients and pending ones. When it already exists, it is rejected to ensure this ID is unique (16 characters max.).

Patient Name	When you enter the ***Patient Name***, a search is done among already listed patients. Names can be duplicated from a drop-down list (30 characters max).
Patient Number	Provide a number to a patient (16 characters max.).
Testing	Switch between DIF and CBC analysis mode. Default type is DIF mode.
Department	Choose from one dynamic list or add a new name (10 characters max.) of patient blood sampling location.
Birthdate	Enter patient date of birth (MM/DD/YYYY).
Age	Age is automatically updated with the patient date of birth.
Gender	Choose from one predetermined list: Male, Female or Blank.
Type	Select blood profile: Standard, Male, Female, Child... (default is standard) using drop-down list.
Physician	Choose a physician name from one dynamic list or add a new name (17 characters max.).
Collect. date	Enter date and time of blood collection in MM/DD/YYYY-HH:mm.
Op.	Operator field is automatically updated by the name of the operator who starts the instrument.
Comment	Use this field to enter comments (50 characters max.).

Color code of the worklist screen

- Blank: This routine analysis is pending.
- Red: This analysis is currently running.
- Green: This routine analysis has been done.
- Blue: This Analysis such as QC, Calibration, Repeatability or blank is pending.
- Pink: This Analysis such as QC, Calibration, Repeatability or blank has been done already.

See also:
- Worklist Icons Description, p.88
- Worklist Keyboard Shortcuts, p.54
- To Create a New Worklist, p.88
- To Open Archived Worklist, p.91
- To Print your Worklist, p.92
- Running Blood Specimen, p.93

3.2. Worklist Icons Description

Print Selected Area: prints selected or all order files in a line mode.

Add New Entry: creates a new order file.

Delete: deletes order files that have not been run yet.

Display Search Screen

Zoom/IList: switches from chart screen to ***Order Entry*** screen (also accessible by double-clicking the entry).

Previous File: displays previous order in the list.

Next File: displays next order in the list.

Rerun Sample: programs rerun of a non validated order. This entry is then duplicated at the end of the ***Worklist*** screen. ***Sample ID***, ***Patient Name***, ***Patient Number***, ***Birthdate*** and ***Gender*** fields become non modifiable.

3.3. To Create a New Worklist

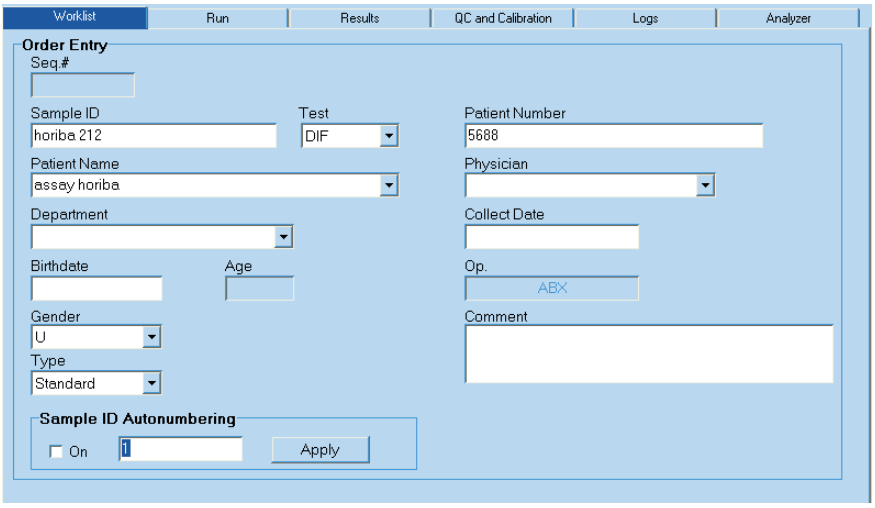
Create a new list of orders everyday before starting analyses and save previous worklist.

*Access: **File** > **New Worklist***

1. Enter the **File** menu and select **New Worklist**.
   An empty worklist is opened.

When a new worklist is created, the previous worklist is automatically stored in archive file.

2. Click the **Add New Entry** icon.
The ***Order Entry*** screen is displayed:

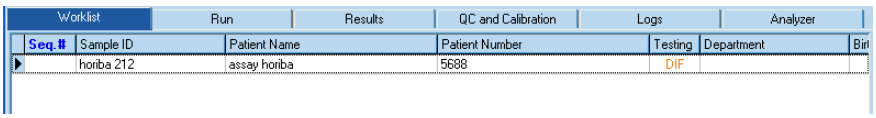


3. Enter the order data:
   a. **Sample ID** (or beep the tube label if you use barcode) and press **Tab** key to move to the next field.

   Select the **On** option and click **Apply** in the ***Sample ID Autonumbering*** area to increment the **Sample ID** field each new entry from a predefined value.

   b. Choose **DIF** or **CBC** from the **Test** drop-down list (default test is DIF).
   c. Enter **Patient Name** (or select a suggested name of the drop-down list).
   d. Select the **Department**.
   e. Enter the **Birthdate**.
   f. Select **Gender** (Male, Female or Unknown).
   g. Select the **Type** (Standard by default)
   h. Enter the **Patient Number**, **Physician**, **Collect Date** and **Comment** if necessary.

4. Double-click the ***Order Entry*** screen or click the **Zoom/List** icon to switch to ***Worklist*** screen.
A new entry is added at the end of the list.



If you do not create a new order, when you run the sample, a new entry is automatically created at the end of the listwith default values:

- **Test** = DIF
- **Gender** = Unknown
- **Type** = Standard
- **Sample ID** = "Autonumbering + n" if option selected or empty.

When you have entered all your orders or received them from the LIS, you may proceed to your sample analyses.

See also:
- To Open Archived Worklist, p.91
- To Print your Worklist, p.92
- Running Blood Specimen, p.93
- Worklist Overview, p.86
- Worklist Icons Description, p.88
- Worklist Keyboard Shortcuts, p.54

3.4. To Sort Orders

Sort the orders in the worklist according to your criterion.

*Access: **Main screen** > **Worklist (tab)***

Analyses already done are always displayed on top of the ***Worklist*** screen. The default order is given by the ***Seq.#*** column.

1. Click once the header of a column to get an increasing order.
   The header turns blue.

2. Click twice the header of a column to get a decreasing order.
   The header turns green.

3. Click three times to set back to default order.

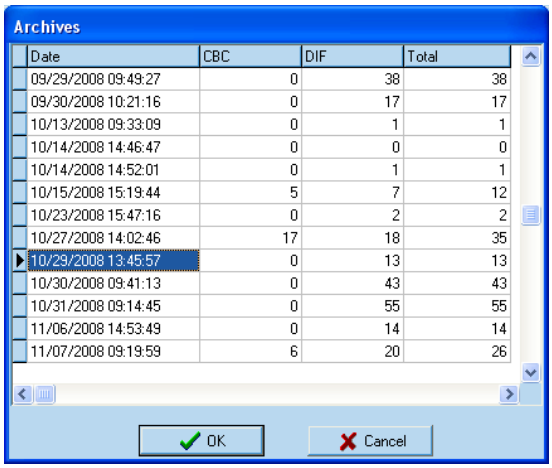
Age and ***Comment*** columns can not be ordered.

3.5. To Open Archived Worklist

Open a prior worklist that has been saved on the Workstation.

*Access: **File** > **Open Archive***

1. Open the ***Archives*** window.
   This one includes the list of all archived worklist and the total number of analyses.



2. Select the date and the worklist you want to display. Click **OK**.
3. Select ***File*** > ***Close Archive*** to close the archived worklist and display the current one.

See also:
- To Create a New Worklist, p.88
- To Print your Worklist, p.92
- Running Blood Specimen, p.93
- Worklist Overview, p.86
- Worklist Icons Description, p.88
- Worklist Keyboard Shortcuts, p.54

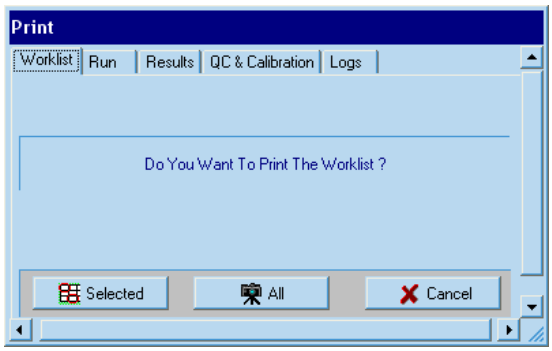
3.6. To Print your Worklist

Print your list of orders to prepare your series of analyses.

*Access: **Worklist** > **Print Selected Area (icon)***

- *Your list of orders have been previously entered or received from the LIS.*
- *You have selected orders to print (see Worklist > To Select the Order to Run chapter).*

1. Open the ***Print*** window and click ***Worklist*** tab.



2. Click **Selected** if you want to print only selected orders.
3. Click **All** if you need to print the entire list.

See also:
- To Create a New Worklist, p.88
- To Open Archived Worklist, p.91
- Running Blood Specimen, p.93
- Worklist Overview, p.86
- Worklist Icons Description, p.88
- Worklist Keyboard Shortcuts, p.54
- To Select the Order to Run, p.93

4. Running Blood Specimen

4.1. To Select the Order to Run

Select the order you want to run in the worklist.

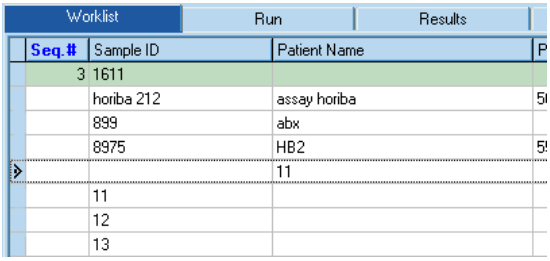
*Access: **Main screen** > **Worklist (tab)***

You have previously defined the orders.

The instrument runs priorly:

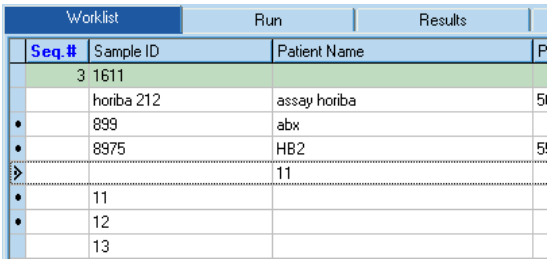
- The first selected order in the worklist.
- If no order is selected, the order following the last that has been run.
- If no order is selected and no analysis has been done yet, the first order of the list.

1. Click the ***Worklist*** tab.
2. To select one order: click the order holding **Ctrl** key.



The selection of the order to run is indicated as shown in the left column of the list.

3. To select several orders : click the orders holding **Ctrl** key.



The selection of the orders to run is indicated as shown in the left column of the list. Selected orders are the next to be run (from the top to the end of the list)

You can now run the specimens that you have selected in the list.

4.2. To Run the Specimen

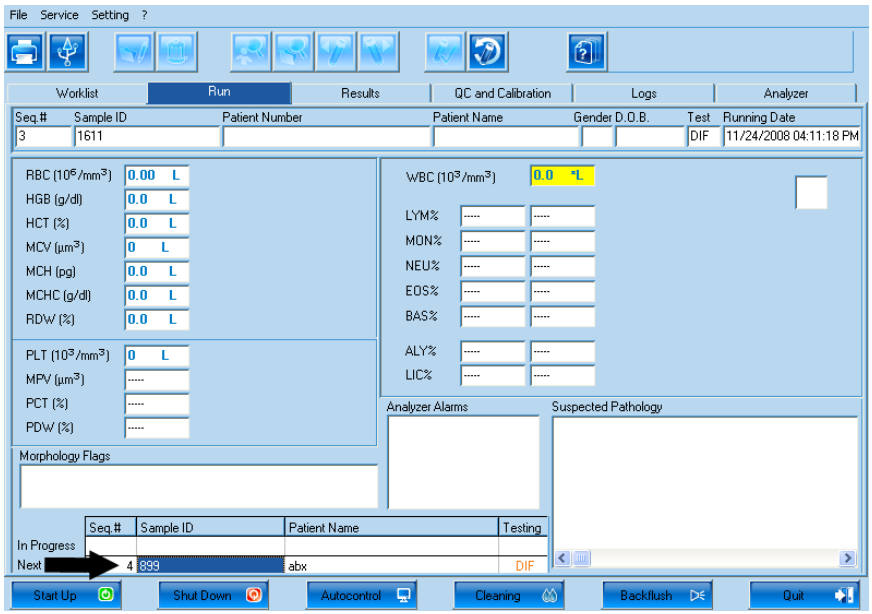
Prepare the specimen and start the analysis on the instrument.

Access: ***Main screen*** *>* ***Run (tab)***

You have checked, selected or printed your list of orders to prepare the specimen. See Worklist chapter.

Recommendations on the analysis mode selection (CBC or DIF)
When selecting CBC analysis, there is no control mode on WBC erroneous countings that may be caused by specific treatments on patients, and WBC/LMNE/BAS balance is automatically disabled (see *Specifications* > *Limitations* chapter and *Workflow* > *Results Interpretation* > *WBC / LMNE / BAS balance* chapters).

1. Enter **Run** tab.



The next specimen to run is shown in the ***Next*** field.

2. If you need to run another specimen than the one shown in the ***Next*** field, you can:
   a. Enter your new sample identification in the ***Sample ID*** field.
   b. Press **Enter** key to confirm.

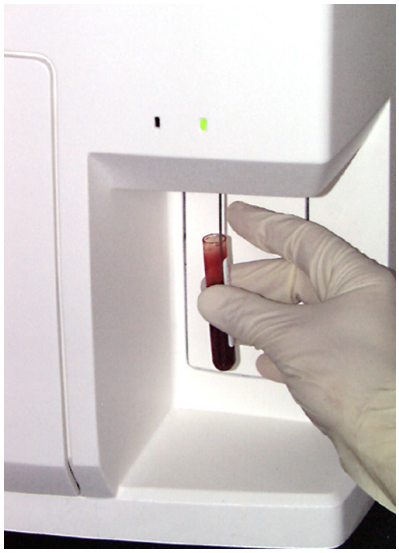
   If this identification is found in the current worklist, the order is automatically associated to this new entry.

3. Prepare your specimen according to the specific instructions detailed in *Specifications* > *Sample Collection and Mixing* chapter.

Blood specimen must be thoroughly and gently mixed (with a gentle up and down and rolling motion), before any measurement.

---

4. Plunge the sampling needle into the specimen tube and press the start bar.



5. Remove the tube when the light indicator stops flashing.
   The LED turns to red.

6. Recap the specimen tube.
   - In the worklist, the order in progress is highlighted in red
   - When the LED turns to green again, the instrument is ready for the next analysis.

You can now review the results of the analysis.

See also:
- Worklist, p.86
- Sample Collection and Mixing, p.35
- Known Interfering Substances, p.41
- WBC / LMNE / BAS Balance, p.117

4.3. Run Menu Overview

*Access: **Main screen** > **Run (tab)***

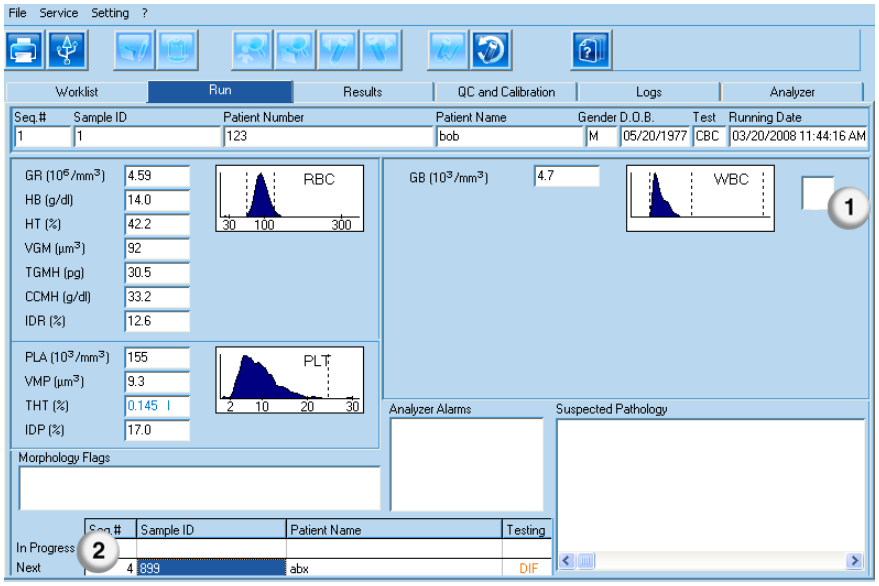
From this screen, you can:

- display the last analysis,
- require a rerun,
- validate results,
- prepare next analysis.

Status of last analysis in the *Run* tab

The status of the displayed analysis is shown by the «Results status indicator» square (1).

Indicator color	Status of the results
White	Specimen results have not been treated yet. Validation and Rerun are possible
Green	Results have already been validated. Rerun can not be required
Red	Rerun has been required. An entry for the new run has been created in the worklist.



The next specimen to run is shown in the ***Next*** field (2).

See also:
- To Rerun Last Analysis from the Run Tab, p.97

4.4. To Rerun a Specimen from the Worklist

Rerun a specimen when you need to verify results.

Access: ***Main screen*** *>* ***Worklist (tab)***

The specimen results must not be validated.

1. Open your worklist.
2. Select the order you want to rerun.
3. Click the **Rerun Sample** icon (see *Worklist > Worklist Icons Description* chapter).
   The entry is then duplicated at the end of the list, and is part of entries to analyze.

You can now prepare the specimen to run the analysis.

See also:
- Worklist Icons Description, p.88

4.5. To Rerun Last Analysis from the Run Tab

Rerun last analysis if you need to verify results.

Access: ***Main screen*** *>* ***Run (tab)***

The specimen results must not be validated.

1. Click ***Run*** tab.
   The last analysis is displayed. The Rerun indicator is white. See *Running Blood Specimen > Run Menu Overview* chapter.

2. Click the **Rerun Sample** icon. See *Worklist > Worklist Icons Description* chapter.
   The entry is then duplicated at the end of the worklist, and is part of entries to analyze.

You can now prepare the specimen to run the analysis.

See also:
- Worklist Icons Description, p.88
- Run Menu Overview, p.96

5. Results Management

5.1. Results Menu Overview

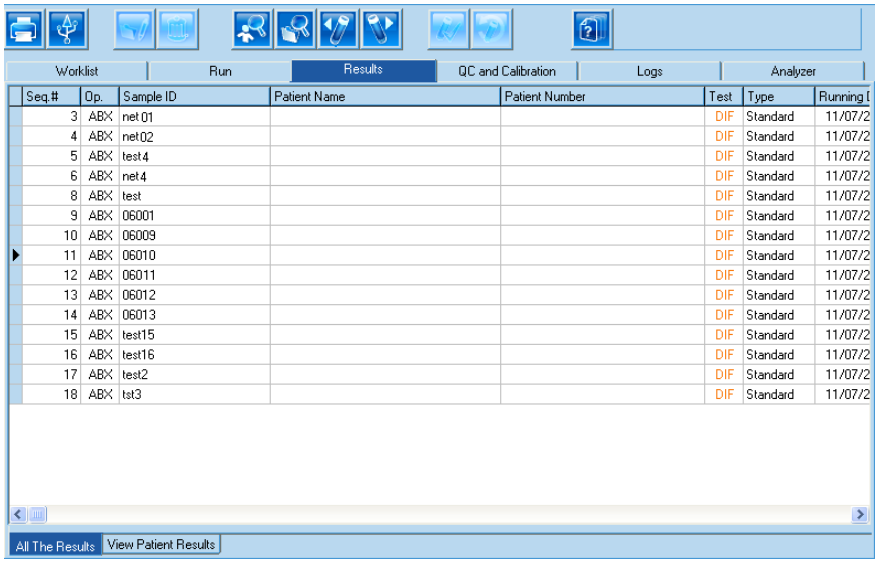
*Access: **Main screen** > **Results (tab)***

This menu is used to review results from the current worklist, to perform a search on patient file, to print or to valid results, to send or to rerun them. Three modes are available:

***View Patients Results* tab**

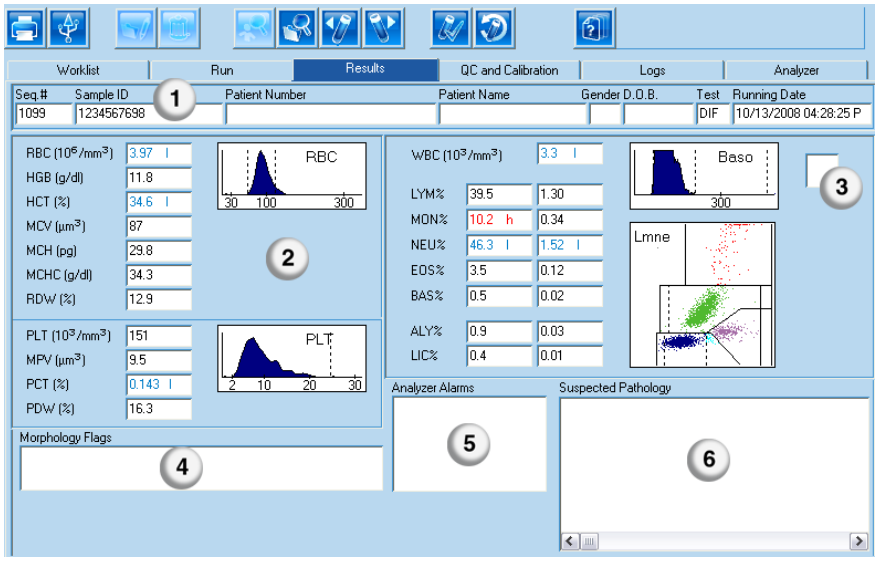
See *Results Management* > *To Search Patients Results* chapter.

***All the Results* tab**



Double click a result line (or click **Zoom/List**) to display the following window:

Review Results in full screen mode



1 = Patient file
2 = DIF results and histograms
3 = Results status indicator (White: not validated yet; Red: pending for rerun; Green: validated)
4 = ***Morphology Flags***: see *Results Interpretation* > *Morphology Flags* chapter.
5 = ***Analyzer Alarms***: see *Results Interpretation* > *Analyzer Alarms* chapter.
6 = ***Suspected Pathology***: see *Results Interpretation* > *Suspected Pathology* chapter.

See also:
- Morphology Flags, p.107
- Analyzer Alarms, p.116
- Suspected Pathologies, p.114
- To Search Patients Results, p.100

5.2. Results Icons Description

Print Selected Area: prints results in a ticket mode or in a line mode (selected or all).

Send Selected Area: sends last, current, selected or all results to the LIS.

Delete: deletes selected result file(s) in the ***View patient results*** screen.

Display Search Screen: searches on **Patient Name** field.

Zoom/IList: switches from list screen to ***View Patient Results*** tab.

Previous File: displays previous results in the list.

Next File: displays next results in the list.

Validate Sample: validates a sample that does not need a rerun.

Rerun Sample: programs rerun of a non validated results.

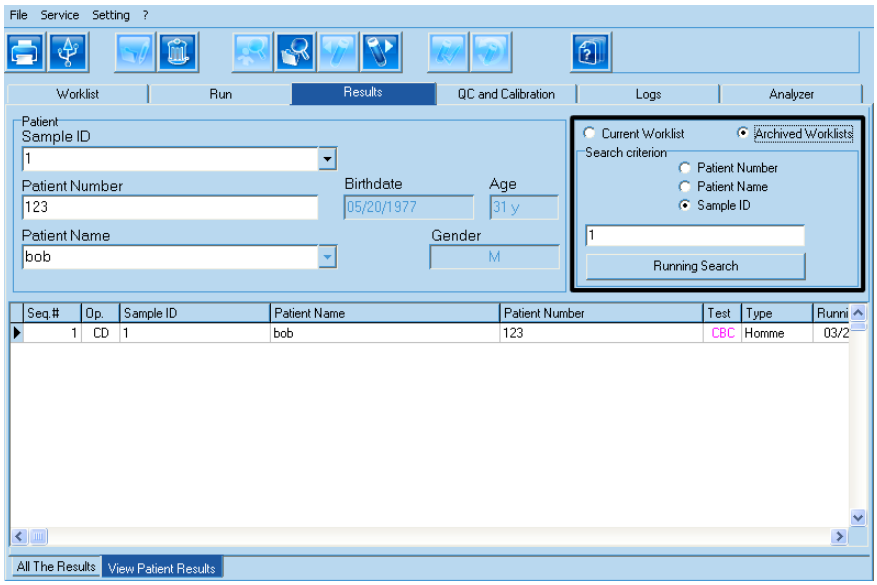
5.3. To Search Patients Results

Search results for a known patient in current worklist or archived worklists.

*Access: **Main screen** > **Results (tab)** > **View Patient Results (tab)***

*You must know **Patient Number** or **Patient Name** or **Sample ID**.*

1. Enter in ***Results*** > ***View Patient Results*** tab.



2. Select one option: **Current Worklist** or **Archived Worklist**.
3. In the ***Search criterion*** area:
   a. Select the item you want to search on: **Patient Number**, **Patient Name** or **Sample ID**.
   b. Type in data to search.
   c. Click **Running Search**.
   If results match with the search criterion defined, they are displayed in a line mode.

   You can double-click a results line to open the results in a full screen mode.

5.4. To Print your Results

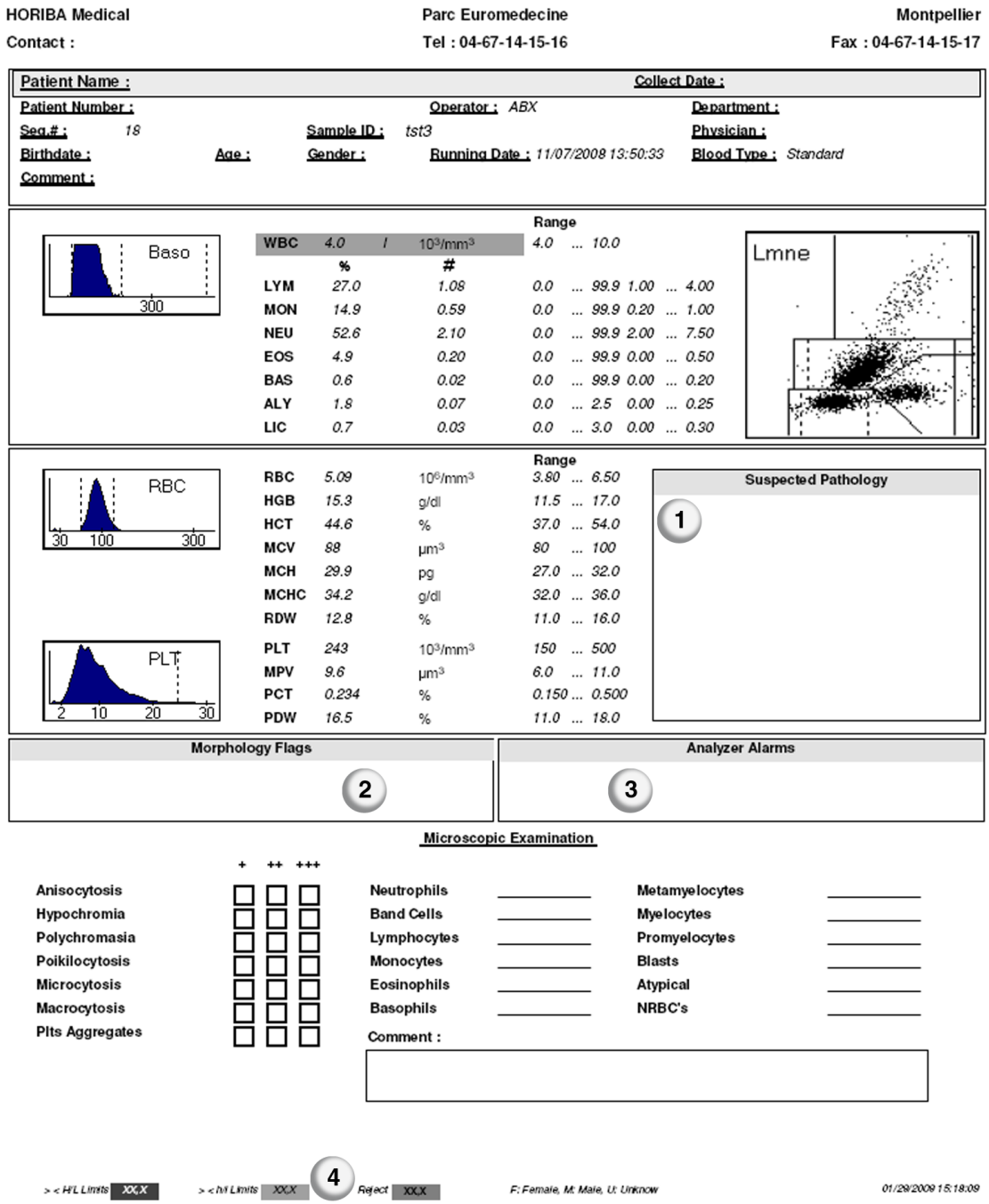
Print your results on request.

Access: ***Main screen*** > ***Results (tab)*** > ***Print Selected Area (icon)***

You have selected the results to print in the ***Results*** > ***All the Results*** *tab.*

1. Click the **Print Selected Area** icon and select ***Results*** tab.
2. Select **List** to print in a line mode or **Ticket** to print in a full page with histograms and matrix.
3. Click **Selected** if you want to print only selected results.
4. Click **All** if you need to print the entire list.

5.4.1. Ticket Printout



1 = Suspected Pathologies
2 = Morphology flags
3 = Analyzer alarms
4 = Grayscale code for results (Out of Panic limits, Out of Normal limits or Rejected results)

More about alarms in *Workflow* > *Results interpretation* chapter.

5.4.2. Line Mode Printout

HORIBA Medical — Parc Euromedecine — Montpellier
Contact : — Tel : 04-67-14-15-16 — Fax : 04-67-14-15-17

Patient Number : — Patient Name : — Gender : — Op. : ABX

Seq.#	Sample ID	Running Date	GB	GR	HB	HT	VGM	TGMH	CCMH	IDR	PLA	VMP	THT	IDP	LYM%	MON%	NEU%	EOS%	BAS%	LYM#	MON#	NEU#	EOS#	BAS#	LYA%	GCI%	LYA#	GCI#
9	06001	11/07/2008 10:36:53	4.9	4.69	13.9	41.3	88	29.5	33.5	12.9	237	8.7	0.206	14.3	33.3	6.4	57.9	2.0	0.4	1.62	0.31	2.82	0.10	0.02	1.5	1.4	0.07	0.07
10	06001	11/07/2008 10:39:11	4.9	4.73	14.0	41.9	89	29.7	33.5	13.0	243	9.1	0.221	15.0	38.6	6.5	52.1	2.4	0.4	1.91	0.32	2.58	0.12	0.02	2.4	1.3	0.12	0.06
11	06001	11/07/2008 10:40:57	5.0	4.68	14.0	41.2	88	29.9	33.9	13.0	234	9.0	0.209	15.3	36.9	6.1	54.4	2.1	0.5	1.83	0.30	2.70	0.10	0.02	2.0	0.7	0.10	0.03
12	06001	11/07/2008 10:43:28	4.9	4.70	13.9	41.6	88	29.6	33.5	12.9	234	9.0	0.210	14.8	34.9	6.9	55.8	1.9	0.5	1.70	0.34	2.72	0.09	0.02	1.9	0.9	0.09	0.04
13	06001	11/07/2008 10:45:27	5.0	4.68	13.9	41.3	88	29.7	33.7	12.9	236	8.8	0.209	14.0	36.8	7.3	53.5	2.0	0.4	1.83	0.36	2.67	0.10	0.02	1.7	0.8	0.09	0.04

> < H/L Limits XX,X > < h/l Limits XX,X Reject XX,X F: Female, M: Male, U: Unknow

Page 1 Printed 12/03/2008 11:39:50

5.5. To Send Results to the LIS

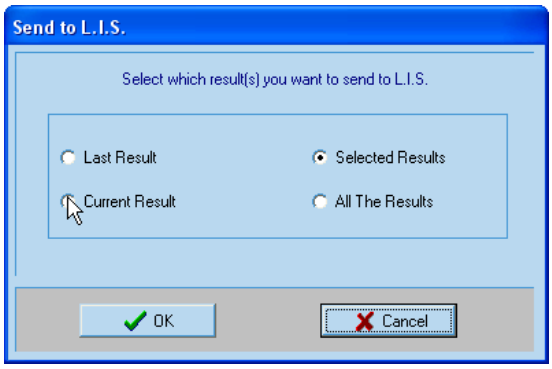
Send your results on request to the LIS (Laboratory Information System).

*Access: **Main screen** > **Results (tab)** > **Send Selected Area (icon)***

After each analysis cycle, results are automatically sent to the LIS according to predefined criteria.

- *You have entered the **Results** > **All the Results** tab.*
- *You have selected results to send.*

1. Click **Send Selected Area** (icon).



2. Select one of the four options: **Last Result**, **Current Result**, **Selected Results** or **All the Results**.
3. Click **OK** to validate.

6. Results Interpretation

6.1. General Flags

6.1.1. Parameter Reject

A parameter reject is shown by «*» and indicates that the result is not coherent. The sample has to be checked (counting problems, poorly maintained instrument, expired reagents, clotted sample, etc.). A rejected result cannot be validated.

Parameter Reject	Triggers if...	Consequences
WBC	The difference between the two WBC counts is higher than the limit set for WBC Reject	«*» on differential parameters
RBC	The difference between the two RBC counts is higher than the limit set for RBC Reject	«*» on MCV, MCH, MCHC
HGB	Three consecutive suspicion flags are triggered on HGB parameter	«*» on MCH, MCHC
HCT	The difference between the two HCT counts is higher than the limit set for HCT Reject	«*» on MCHC
PLT	The difference between the two PLT counts is higher than the limit set for PLT Reject or SCL flag or MICP flag and not able to define the mobile threshold's position between 18 and 25 fL (see *Platelet flags* chapter) or SCH flag	«*» on PDW, MPV, PCT
LMNE matrix	Correlation between resistive and optical measurements < 50% (adjustable)	«*» on all the differential parameters

See also:
- Platelet Flags, p.107

6.1.2. Suspicion

A suspicion on a parameter is shown by «!». The sample must be rerun.

HGB suspicion

- On each analysis an HGB reference value is set (mean of the last 3 HGB blank tests on diluent).
  If difference between new HGB blank test on cycle and HGB reference value > HGBB# (set by the user, see *Settings* > *Setting Menu* > *Type parametering* chapter) then a suspicion flag is triggered on HGB parameter.

- Other test is performed each analysis on HGB measures to evaluate their consistency. Computation obtained on this test must be within acceptable ranges (< HGBM% limit ; set by the user). if this test has failed, «!» is also associated with HGB result.

Platelet suspicion

Conditions	Consequences	Action
If PLT < 120x10^3/mm^3 (in CBC mode only)	«!» on PLT (applied on patients results only)	The result is presumed erroneous, it must be checked with a rerun sample or with a reference method if the second result is still flagged
If PLT < 120x10^3/mm^3 + PDW > 20 (in CBC and DIF mode)		

WBC suspicion

Conditions	Consequences	Action
LMNE+ or LMNE- or BASO+ flag	«!» on WBC (applied on patients results only)	The result is presumed erroneous, it must be checked with a rerun sample or with a reference method if the second result is still flagged.
L1 flag	«!» on WBC and on absolute values of the differential parameters (applied on patients results only)	

LMNE suspicion

Conditions	Consequences	Action
«!» flag on WBC	«!» on BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY%, LIC#, LIC% parameters (applied on patients results only)	The result is presumed erroneous, it must be checked with a rerun sample or with a reference method if the second result is still flagged.
HGB > 17,5 g/dL or invalid «---»	«!» is generated on BAS#, BAS%, LYM#, LYM%, MON#, MON%, NEU#, NEU%, EOS#, EOS% parameters (applied on patients results only)	
LMNE+ or LMNE- or MB or LN flag	«!» on BAS#, BAS%, LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY%, LIC#, LIC% parameters	
LL flag	«!» on LYM#, LYM%, MON#, MON%, EOS#, EOS%, NEU#, NEU%, ALY#, ALY %, LIC#, LIC% parameters	
RN flag	«!» on NEU#, NEU%, LIC#, LIC% parameters	
RM flag	«!» on MON#, MON%, NEU#, NEU%, LIC#, LIC% parameters	
NL flag	«!» on LYM#, LYM%, NEU#, NEU% parameters	
MN flag	«!» on ALY#, ALY%, LIC#, LIC% parameters NEU%, NEU#, MON% and MON# are reported to «---»	
NE flag	«!» on LIC% and LIC# NEU%, NEU#, EOS% and EOS# are reported to «---»	

6.1.3. Normal and Panic Ranges

Panic and normal ranges are defined for each blood type in ***Setting*** > ***Type Parametering*** menu.

- h : Indicates that the result is above the normal limit set by the user.
- l : Indicates that the result is below the normal limit set by the user.
- **H** : Indicates that the result is above the panic limit set by the user.
- **L** : Indicates that the result is below the panic limit set by the user.

See also:
- Type Parametering, p.125

6.1.4. Results Exceeding Instrument Capacities

Use the instrument's diluent to dilute the sample if a "---- D" flag occurs on WBC or HCT.

Parameter	Linearity Limits	Visible Range	> Visible Range (displayed)	> Visible Range (transmitted or printed out)
WBC	«result»	«result+D»	DIL	--.-- + D
RBC	«result»	«result+D»	DIL	--.-- + D
HGB	«result»	«result+D»	DIL	--.-- + D
HCT	«result»	«result+D»	DIL	--.-- + D
PLT	«result»	«result+D»	DIL	--.-- + D

Results displayed and printed out: «PLT-C» indicates the triggering of the PLT extended linearity mode for an HGB < 2g/dL & PLT > 15 x 10^3/mm^3 between 1900 x 10^3/mm^3 and 2800 x 10^3/mm^3.

Results transmitted: «C» indicates the triggering of the PLT extended linearity mode for an HGB < 2g/dL & PLT > 15 x 10^3/mm^3 between 1900 x 10^3/mm^3 and 2800 x 10^3/mm^3.

See *Workflow* > *Results Interpretation* chapter to know more about these flags.

Whole blood parameter results within visible range will still give a result value with a "**D**" flag. These results require a dilution (or PRP analysis for PLT) of the sample with the instrument's diluent.

See also:
- PLT-C Flag, p.118
- Linearity Limits, p.32

6.2. Morphology Flags

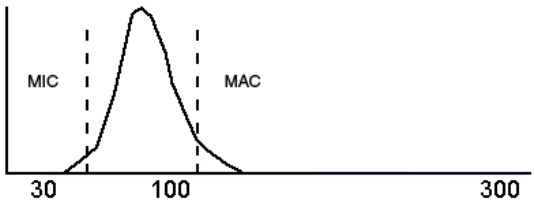
6.2.1. Erythrocyte Flags

See also:
- Type Parametering, p.125

6.2.1.1. MIC and MAC Flags

MIC and **MAC** flags are triggered off when the percentage of cells counted respectively in the MIC area or MAC area versus the total number of RBC is higher than the limit set by the user.

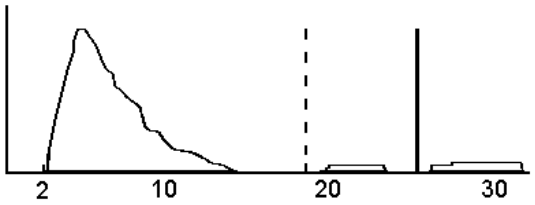
- **Value for *Standard* type is MIC = 5%**
- **Value for *Standard* type is MAC = 45%**



These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.2. Platelet Flags

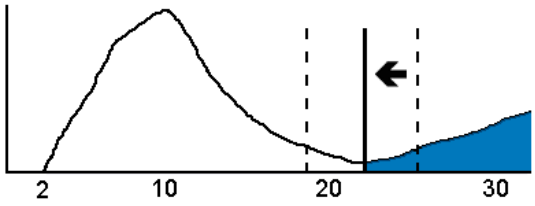
The PLT histogram contains 256 channels between 2 fL and 30 fL. A mobile threshold (at 25 fL by default) moves according to the microcyte population present in the platelet analysis area.



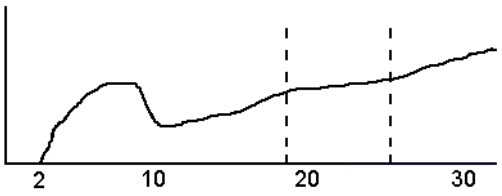
See also:
- Parameter Reject, p.104

6.2.2.1. MICP Flag

An excessive number of particles on the right side of the threshold area (after 25 fL) generates the MICP (Microcytes) flag. The mobile threshold looks for a valley between 18 fL and 25 fL (standard area). It indicates the presence of microcytes in the counting area of platelets. If associated with a PLT reject«*», then PLT results are not reliable.



If the mobile threshold cannot position itself in the standard area (between 18 fL to 25 fL), a PLT reject «*» and a MICP flag is generated. The PLT results are not reliable. Verify the result using a Platelet Rich Plasma (PRP) or a manual platelet count.

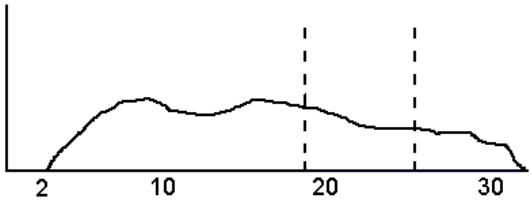


6.2.2.2. SCH Flag

If the mobile threshold cannot be positioned (no valley between the PLT and RBC histograms) the SCH (schistocytes) flag is generated, associated with a PLT reject «*», then PLT results are not reliable.

Suspected abnormalities:

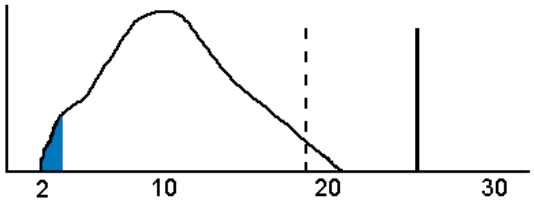
- Schistocytes
- Platelet aggregates



If platelet aggregates or platelet clumping is suspected, patient sample should be redrawn in a sodium citrate tube. Do not *vortex* the sample.

6.2.2.3. SCL Flag

The SCL (Small Cell) flag indicates the presence of small cells in the 2 fL and 3 fL zone. A second analysis should be carried out and the results verified.



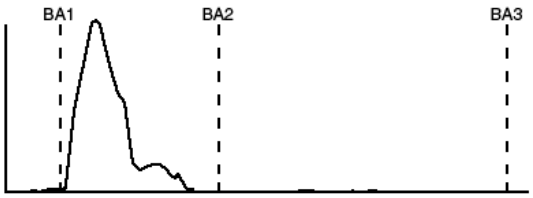
SCL flag belongs to the ***Analyzer Alarms*** flags category.

6.2.3. Differential Leukocyte Flags

6.2.3.1. L1 Flag

L1 Flag can be triggered out either on DIF or CBC mode.

L1 flag is established according to the ratio of the cells counted between the 0 channel and BA1. It indicates a presence of abnormal number of cells in this area in relation to the total number of leukocytes



Suspected abnormalities:

- PLT aggregates
- NRBCs

Values for L1 *Standard* type are %3 and #200

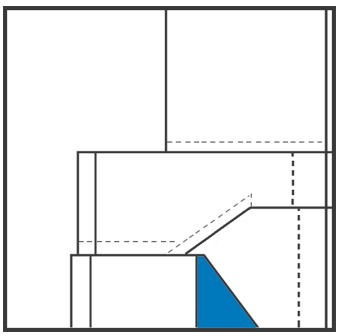
These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

DIF mode enhances detection of certain anomalies as it provides two additional flags LL and LL1 compared to CBC mode with only L1 flag (large platelet aggregates and/or erythroblasts for example that are beyond electronic threshold). HORIBA Medical highly recommends to use DIF mode that gives the best reliability in these anomalies detection.

6.2.3.2. ALY flag

Atypical LYmphocytes

Presence of a significantly large population of cells located on the right-hand side of the lymphocyte area. The atypical lymphocytes flag appears when the number of counted particles in this area is higher than the limit set up in **ALY#** or when the number of counted particles regarding the total number of WBC is above the **ALY%** limit.



Suspected abnormalities:

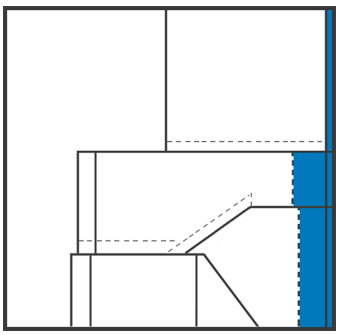
- Large lymphocytes
- Reactive lymphoid forms
- Stimulated lymphocytes
- Plasmocytes

Values for ALY *Standard* type are %2.5 and #0.25

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.3. LIC flag

Large Immature Cells



Presence of a significantly large population of cells located on RN + RM + channel 127 areas. The large immature cells flag appears when the number of counted particles in this area is higher than the limit set up in **LIC#** or when the number of counted particles regarding the total number of WBC is above the **LIC%** limit.

Suspected abnormalities:

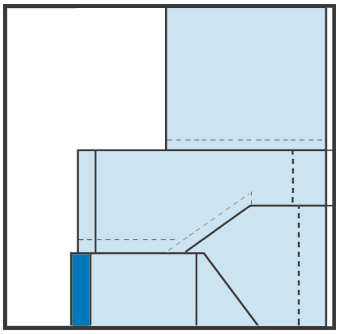
- Promonocytes, monoblasts, hyper basophilic monocytes
- Metamyelocytes, myelocytes, promyelocytes
- Blasts, large monocytes
- Large neutrophils

Values for LIC *Standard* type are %3 and #0.3

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.4. LL flag

Left Lymphocytes



Presence of a significantly large population of cells on the left-hand side of the lymphocyte area. The left lymphocytes flag appears when the number of counted particles is higher than the limit set up in **LL#** or when the number of counted particles versus the number of WBC exceeds the **LL%** limit.

This flag is associated with an «!» on:

- LYM% LYM#
- NEU% NEU#
- MON% MON#
- EOS% EOS#
- ALY% ALY#
- LIC% LIC#

Suspected abnormalities

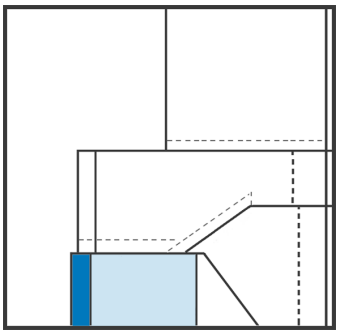
- Platelet aggregates
- Small lymphocytes
- Erythrocyte membrane resistant to lysis (stroma)
- Erythroblasts

Values for LL *Standard* type are %100 and #50

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.5. LL1 flag

Left Lymphocytes 1



Presence of a significantly large population of cells on the left-hand side of the lymphocyte area. The left lymphocytes 1 flag appears when the number of counted particles is higher than the limit set up in **LL1#** and when the number of counted particles in **LL** regarding the total number of lymphocytes exceeds the **LL1%** limit.

Suspected abnormalities

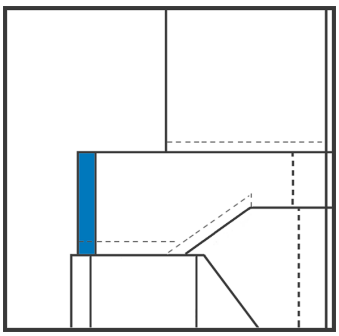
- Platelet aggregates
- Small abnormal lymphocytes
- Erythrocyte membrane resistant to lysis (stroma)
- Erythroblasts

Values for LL1 *Standard* type are %5 and #45

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.6. LN flag

Left Neutrophils



Presence of a significantly large population of cells located in the left-hand side of the neutrophil area. The left neutrophils flag appears when the number of counted particles in this area is higher than the limit set up in **LN#** or when the number of counted particles regarding the total number of WBC is above the **LN%** limit.

This flag is associated with an «!» on all WBC differencial parameters.

Suspected abnormalities

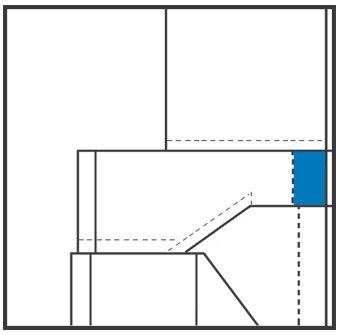
- Neutrophil destruction due to incorrect storage of the sample or old sample
- Contamination, stroma or platelet aggregates

Values for LN *Standard* type are %2.5 and #999

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.7. RN flag

Right Neutrophils



Presence of a significantly large population of cells located on the right side of the neutrophil area (high LIC). The right neutrophils flag appears when the number of counted particles in this area is higher than the limit set up in **RN#** or when the number of counted particles regarding the total number of WBC is above the **RN%** limit.

This flag is associated with an «!» on:

- NEU% NEU#
- LIC% LIC#

Suspected abnormalities

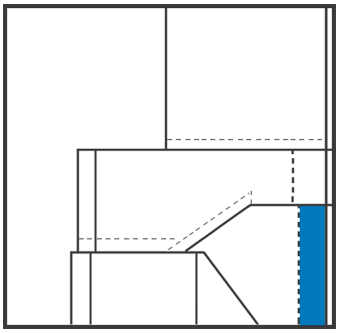
- Large neutrophils
- Immature cells from granulocyte hemopoiesis (metamyelocytes, myelocytes, promyelocytes)

Values for RN *Standard* type are %1.1 and #999

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.8. RM flag

Right Monocytes



Presence of a significantly large population of cells located on the right-hand side of the mococyte area (low LIC). The right monocytes flag appears when the number of counted particles in this area is higher than the limit set up in **RM#** or when the number of counted particles regarding the total number of WBC is above the **RM%** limit.

This flag is associated with an «!» on:

- NEU% NEU#
- MON% MON#
- LIC% LIC#

Suspected abnormalities

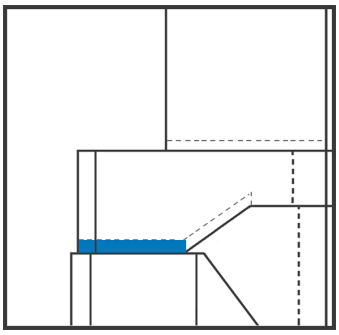
- Large monocytes
- Hyperbasophilic monocytes
- Myelocytes or promyelocytes
- Large blasts

Values for RM *Standard* type are %1.1 and #999

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.9. NL flag

Neutrophils / Lymphocytes



Presence of a significantly large population of cells located in the separation threshold area between lymphocytes and neutrophils. The neutro/lympho flag appears when the number of counted particles is higher than the limit set up in **NL#** or when the number of counted particles regarding the total number of WBC exceeds the **NL%** limit.

This flag is associated with an «!» on:

- LYM% LYM#
- NEU% NEU#

Suspected abnormalities

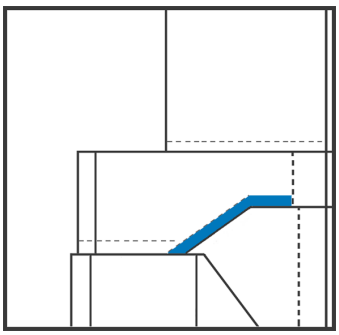
- Small neutrophils without granules and/or slightly segmented
- Lymphocytes with a segmented nucleus or Activated lymphocytes
- Neutrophils with membrane weakness

Values for NL *Standard* type are %3 and #120

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.10. MN flag

Monocytes / Neutrophils



Presence of a significantly large population of cells located in the separation threshold area between monocytes and neutrophils. The mono/neutro flag appears when the number of counted particles in this area is higher than the limit set up in **MN#** or when the number of counted particles in **MN** versus the total number of WBC is above the **MN%** limit.

This flag is associated with an «!» on:

- ALY% ALY#
- LIC% LIC#

NEU%, NEU#, MON% and MON# are reported to «---».

Suspected abnormalities

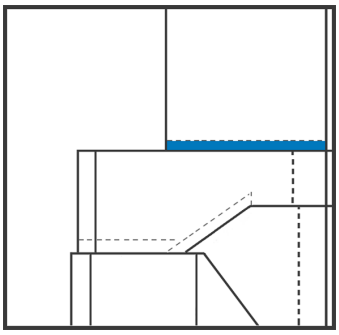
- Monocytes having granules in their cytoplasm or hyperbasophilic monocytes
- Young neutrophils with non-segmented nuclei (bandcells)

Values for MN *Standard* type are %100 and 120#

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.11. NE flag

Neutrophils / Eosinophils



Presence of a significantly large population of cells located in the separation area between neutrophils and eosinophils because of a superimposition of the two populations. The neutro/eosino flag appears when the number of counted particles in this area is higher than the limit set up in **NE#** or when the number of counted particles regarding the total number of WBC is above the **NE%** limit.

This flag is associated with an «!» on LIC% and LIC# NEU%, NEU#, EOS% and EOS# are reported to «---».

Suspected abnormalities

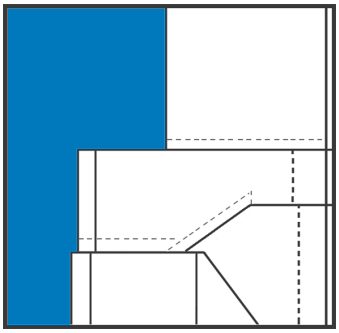
- Young eosinophils
- Giant hypersegmented neutrophils
- Eosinophils with low intracytoplasmic material
- Immature cells
- Neutrophils with cytotoxic granulations

Values for NE *Standard* type are %1.1 and #60

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.2.3.12. NO flag

Background Noise



This flag occurs when the number of counted particles in the background noise area is higher than the limit set up in **NO#** or when the number of counted particles versus the total number of WBC is above the **NO%** limit.

Suspected abnormalities

- Platelet aggregates
- Large number of platelets
- Erythrocyte membrane resistant to lysis (stroma)
- Erythroblasts
- Background noise

Values for NO *Standard* type are %100 and #120

These flag values can be defined for each blood type in ***Setting*** > ***Type Parametering*** > ***Alarms and Curve Thresholds*** tab.

6.3. Suspected Pathologies

«Suspected Pathologies» messages can be displayed and/or printed out. The triggering conditions are linked to the laboratory limits set by the user.

These messages indicate a possible pathological disorder and should be used to assist with quick and efficient screening of abnormal samples along with detection of certain conditions that lead to specific diagnosis. It is recommended to use known reference methods to confirm diagnoses.

6.3.1. WBC Messages

Message	Triggered if...
Leukocytosis	WBC > WBC H
Leukopenia	WBC < WBC L
Lymphocytosis	LYM # > LYM # H or if LYM % > LYM % H
Lymphopenia	LYM # < LYM # L or if LYM % < LYM % L
Neutrophilia	NEU # > NEU # H or if NEU % > NEU % H
Neutropenia	NEU # < NEU # L or if NEU % < NEU % L
Eosinophilia	EOS # > EOS # H or if EOS % > EOS % H
Myelemia	NEU % > NEU % H and LIC # > LIC # H
Large Immature Cell	LIC # > LIC # H or LIC % > LIC % H
Atypic Lymphocyte	ALY # > ALY # H or ALY % > ALY % H
Left Shift	(MN or NL) and RN
Monocytosis	MON # > MON # H or if MON % > MON % H
Basophilia	BAS # > BAS # H or if BAS % > BAS % H
Blasts	BAS # > BAS # H and LIC # > LIC # H and RM
Interpretation Not possible	WBC < 0,1x10^3/mm^3 or WBC > 85.0x10^3/mm^3 or CO alarm

- «H» means High panic limit
- «L» means Low panic limit

6.3.2. RBC Messages

Message	Triggered if...
Anemia	HGB < HGB L
Anisocytosis	RDW > RDW H
Microcyte	MIC Flag
Macrocyte	MAC Flag
Hypochromia	MCHC < MCHC L
Cold Agglutinin	MCHC > MCHC H and WBC < 91.3x10^3/mm^3
Microcytosis	MCV < MCV L
Macrocytosis	MCV > MCV H
Erythrocytosis	RBC > RBC H
Interpretation Not possible	RBC < 0,01x10^6/mm^3 or RBC reject (or RBC>0.03 during Startup)

- «H» means High panic limit
- «L» means Low panic limit

6.3.3. PLT Messages

Message	Triggered if...
Thrombocytosis	PLT > PLT H
Thrombocytopenia	PLT < PLT L
Microcytosis	MICP Flag
Schizocytes	No threshold between RBC and PLT on the curves.
Small Cell	Small cells at the beginning of the platelet curve.
Platelets Aggregate	**Condition 1:** PLT < 150x10^3/mm^3 + WBC reject or NO + PDW > 20 or NO + MPV > 10 or NO + PLT < 150x10^3/mm^3 or NO + WBC reject or (L1 or LL1) + PDW > 20 or (L1 or LL1) + MPV > 10 or (L1 or LL1) + PLT < 150x10^3/mm^3 or PDW > 20 + PLT < 120x10^3/mm^3 (in CBC mode only, a suspicion flag «!» is triggered on PLT)
NRBCs	**Condition 2:** LL or WBC reject + L1 or WBC reject + LL1
Platelets Aggregate Erythroblasts	**If conditions 1 and 2 are not satisfied:** and if L1 or LL1 or WBC reject
Macroplatelets	MPV > 11
Interpretation Not possible	PLT < 5,0x10^3/mm^3 or PLT reject (or SCL alarm during Startup)

- «H» means High panic limit
- «L» means Low panic limit

See also:
- Normal and Panic Ranges, p.106
- SCL Flag, p.119
- NO flag, p.114

6.4. Analyzer Alarms

6.4.1. NO Flag

More about NO Flags in *Morphology Flags* > *Differential Leukocyte Flags* chapter.

See also:
- NO flag, p.114

6.4.2. CO Flag

Meaning	Poor correlation
Conditions	The percentage of validated cells is abnormally low: correlation between resistive and optical measurements is < 50%
Suspected Abnormalities	■ Stroma interfering with measurement ■ Strong pollution ■ Incorrect adjustment of the optical bench
Consequences	All the matrix parameters are reported to «--.--»

6.4.3. Baso+ Flag

Conditions	Baso+ flag occurs on DIF mode only. BAS % > 50 %
Consequences	The Basophils are not taken away from the matrix populations and BAS % and BAS # are reported to «---»

6.4.4. MB Flag

Meaning	Mono BAS
Conditions	MB flag occurs on DIF mode only. The percentage of basophils found in the BAS channel is above the percentage of Lympho / Mono / Neutro raw counts found on the matrix channel.
Possible triggers	■ Small basophils in the ALY area ■ Blasts ■ Contamination of the basophil channel
Consequences	■ «!» on all the % and # matrix parameters ■ MONO and BAS in # are reported to: «--.--»

6.4.5. WBC / LMNE / BAS Balance

During the initial count of the WBC in the WBC / BAS chamber, a second WBC count is performed from the injected volume through the LMNE optical flowcell. The two counts are compared.

If the difference between the LMNE and WBC / BAS counts is higher than the defined threshold, depending on the quantity of cells measured, a LMNE+ or a LMNE- flag is generated.

- **The WBC count is within 0 and 2501**:

  If the WBC / LMNE count is 50% > WBC / BAS count then LMNE+ flag is generated.
  If the WBC / LMNE count is 50% < WBC / BAS count then LMNE- flag is generated.
- **WBC count is within 2501 and 8000**:

  If the WBC / LMNE count is 20% > WBC / BAS count then LMNE+ flag is generated.
  If the WBC / LMNE count is 20% < WBC / BAS count, then LMNE- flag is generated.
- **WBC count is higher than 8000**:

  If the WBC / LMNE count is 15% > WBC / BAS count then LMNE+ flag is generated.
  If the WBC / LMNE count is 15% < WBC / BAS count then LMNE- flag is generated.

The WBC / BAS channel is considered as a reference and is used to calibrate the WBC / LMNE channel. The calculated ratio between the two channel calibration coefficients is stable (except during technical intervention). In any case, it is the WBC / BAS result that is reported.

The WBC balance flags (LMNE+ and LMNE-) are activated only if:

- the test selected is «DIF»
- the WBC / LMNE / BAS balance has been enabled by an HORIBA Medical technician.

These flags are associated with an «!» on all differential parameters (% and #)
CBC mode Limitations: The WBC / LMNE / BAS balance flag indicates an instrument defect or highlights a known interference (see *Specifications* > *Limitations* chapter). In case of pathology which treatments weaken the leucocytic membranes, the agent of lysis of WBC channel can damage the cells and give a lower leukocytes counting. The LMNE+ flag is then triggered off, and a suspicion is associated to the WBC results. It is recommended not to disable WBC balance flag and to work in DIF mode for all samples that can present this possible interference. Selecting the CBC mode disables this control mode. It is recommended to use this mode for patients not presenting this type of interference.

See also:
- Limitations, p.41

6.4.6. PLT-C Flag

Meaning	Platelet Concentrated
Conditions	Indicates the triggering of the «PLT extended linearity mode» for an HGB < 2g/dL & PLT > $15x10^3/mm^3$ between $1900x10^3/mm^3$ and $2800x10^3/mm^3$.
Display and printout	«PLT-C»
Sending to LIS	«C»

See *General Flags* > *Results Exceeding Instrument Capacities* chapter.

See also:
- Results Exceeding Instrument Capacities, p.34

6.4.7. SCL Flag

More about Small Cells in *Morphology Flags* > *Platelet Flags* chapter.

See also:
- Platelet Flags, p.107

7. End of Day

7.1. Instrument Inactivity and Automatic Cleaning

Cleaning cycles are automatically required when:

- The instrument has run xx analysis cycles from the date changing. xx is defined by the user and set to 75 by default (see *Settings* > *Setting menu* chapter).
- The instrument has not been used for **two** hours.
- The instrument has not been used for **four** hours. In this case a Startup cycle is required before running the cleaning cycle.

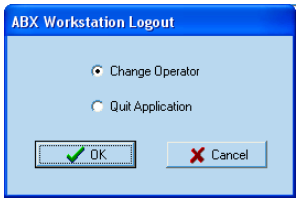
It is mandatory to power down the system if not used for more than a 36 hour period. This eliminates the possibility of the dilution chambers evaporating and causing startup problems.

7.2. To Change Operator

Switch from one operator to another.

1. From the main screen, click **Quit**:

2. Choose the **Change Operator** option:



3. Click **OK** to validate.
The ***Pentra 60 Range / Workstation*** window is displayed.

4. Log in with a new user account as described in *Workflow* > *Start of Day* > *To Log in the Application* chapter.

See also:
- To Log in the Application, p.76

7.3. Stopping the Instrument

7.3.1. To Perform a Shutdown

Perform an instrument shutdown before ending your work session.

*Access: **Main screen** > **Shut Down (icon)***

The main screen has to be displayed.

1. Click **Shut Down**:


2. Wait during shutdown cycle.

Once the shutdown is completed, the instrument can be switched off.

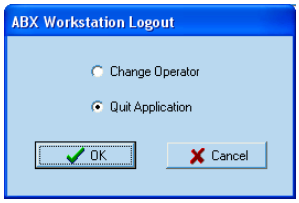
7.3.2. To Switch Off the Instrument

Switch off the instrument and workstation at the end of the day.

A shutdown cycle must have been performed.

1. Click **Quit** to quit the application:


2. In the ***ABX Workstation Logout*** window, choose the **Quit Application** option:



3. Click **OK** to validate.
4. Wait during application is closing. The computer is restarting.
5. When the ***Log On to Windows*** window is displayed, click **Shut Down...**, then click **OK** to validate.
6. Switch off the instrument.

7.3.3. To Switch Off the Printer

Switch off the printer at the end of the day.

1. Check that no printout has been launched.
2. Switch off the printer.

Settings

1. Setting Menu

1.1. QC and Calibration

- Select barcode identification for Control and Calibration sample.
- Choose XB mode.
- Set CV ranges for QC, Calibration and Repeatability.

Access: ***Setting*** > ***QC and Calibration***

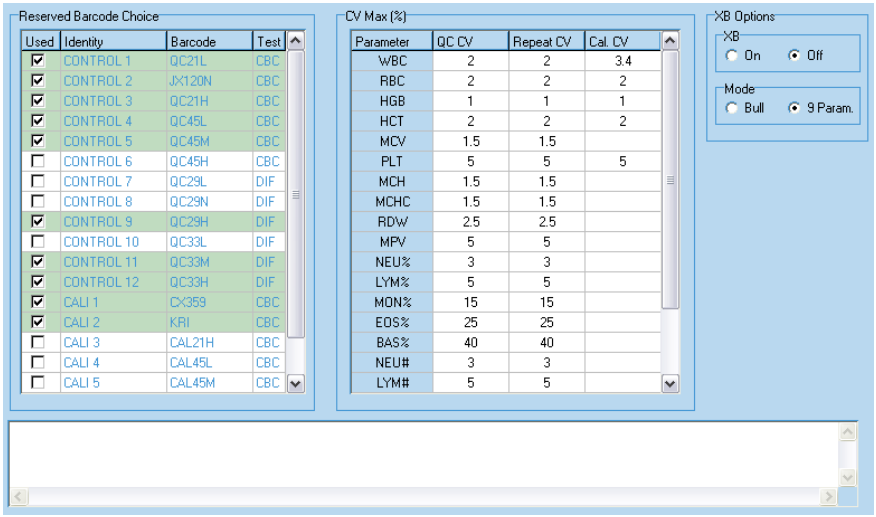
Reserved Barcode Choice: Select the automatic checkboxes of the barcodes associated to the QC lots to automatically assign the results of these lots (treatment and archiving) in the QC or Calibration menu (the row turns to green when selected). If not selected, the use of this barcode has no effect on the passage of the cycle. The result then switches to the routine environment.

CV Max (%): Adjustment of the QC, Repeatability and Calibration admissible Coefficients of variation expressed in %.

Variation coefficients calculation for each parameter is done with unrounded values.

XB Options:

- **XB**: Activates (On) or deactivates (Off) XB function
- **Mode**: three parameters (Bull) MCV, MCH and MCHC, or nine parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT.



1.2. Type Parametering

- Define Blood types.
- Assign a set of pathological limits, alarms levels, matrix thresholds to each type.

Assigning a type to a sample enhances the result rendering quality. Internal parameters used in the result calculation are adjusted to the sample according to known hematological criteria.

Twenty different blood types can be created. Type is defined by a set of :

- Thresholds that trigger «Suspected Pathologies»
- Panic and normal ranges on parameters
- Alarms levels
- Matrix and histograms thresholds

This access is protected by a password. Enter **421** and click **OK** to validate.

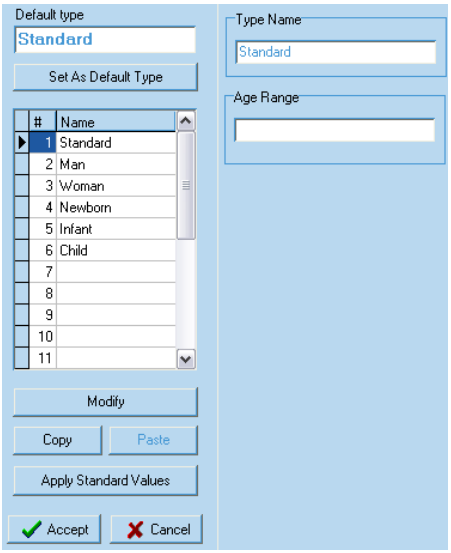
See also:
- Results Interpretation, p.104
- Instrument Default Settings, p.142

1.2.1. To Create a Blood Type

- Define or modify a blood type.
- Apply standard values or copy values from another type.
- Set this type by default.

Access: ***Setting*** > ***Type Parametering***

1. Select a field in the list and click **Modify**.



2. Enter the password and type in a new name.
3. Click **Accept** to validate. You can either apply standard values or values from another type:
   a. To copy - paste types, select the type you want to copy, click **Copy** and place the cursor in an empty field of the list, or on the type you want to apply values. Then click **Paste**.
   b. To apply standard values, select a type in the list and click **Apply Standard Values**.
4. To set a type as default, select it in the list and click **Set As Default Type**.

Default "Standard" type setting is not modifiable. Names of the five following types cannot be modified neither.

You can now set the pathological limits, alarms levels and/or matrix thresholds of a type.

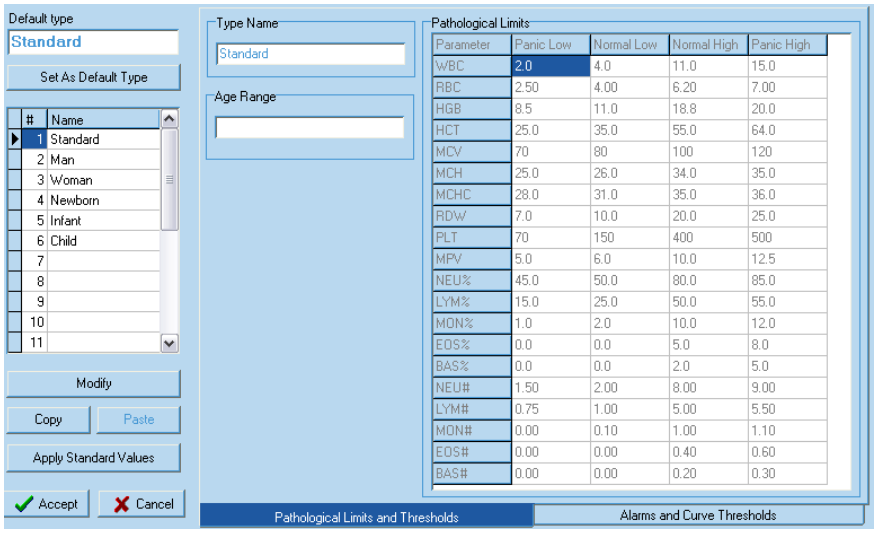
1.2.2. To Set Pathological Limits

Define Normal and Panic limits of each blood type.

*Access: **Setting** > **Type parametering** > **Pathological Limits and Thresholds (tab)***

You have already defined a new type, or you want to modify an existing one.

1. Select the type you want to modify in the list.



2. Click **Modify**.
3. Enter the password and change the value in the ***Pathological Limits*** table.
4. Click **Accept** to validate.

Laboratory levels can be set by the operator according to its own specifications.
Results that exceed the **Normal** limits are identified with a flag:

- **h** for results above the upper limit
- **l** for results below the lower limit

Results that exceed the **Panic** limits are identified with a flag:

- **H** for results above the upper limit
- **L** for results below the lower limit

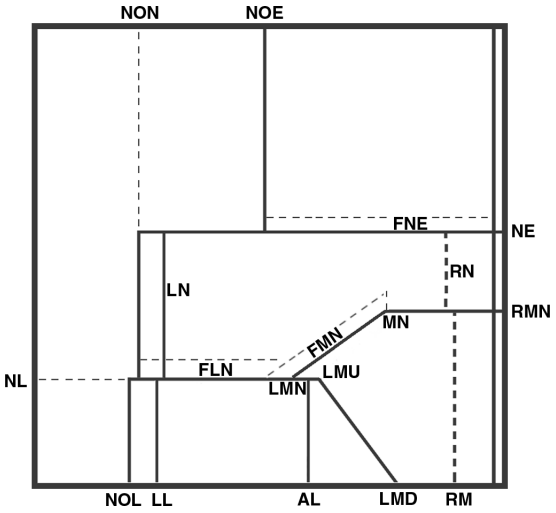
You can now adjust the alarms levels and the thresholds of this type.

1.2.3. Curves and Matrix Thresholds

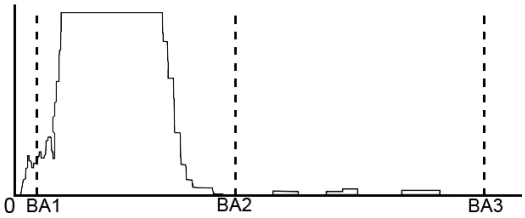
Each axis of the matrix (X and Y) is divided into 128 channels numbered from 0 to 127. The threshold adjustment is expressed in channels.

You can adjust the LMNE matrix thresholds to:

- Improve the separation between different cell populations which can vary according to the anti-coagulant in use or instrument internal adjustment.
- Modify the flag areas in one way or another to improve their detection sensitivity. In this case, the numeric adjustment of the concerned flag must also be readjusted (see Alarm levels).
- Modify one or several matrix areas in order to define more precisely a specific population for research purposes.



All the WBCs are counted between the electrical thresholds, from <0> to <BA3>. The basophils are located from threshold <BA2> to threshold <BA3>.



More information about alarms, curves and thresholds in *Workflow* > *Results Interpretation* chapter.

1.2.4. To Set Alarms Levels and Thresholds

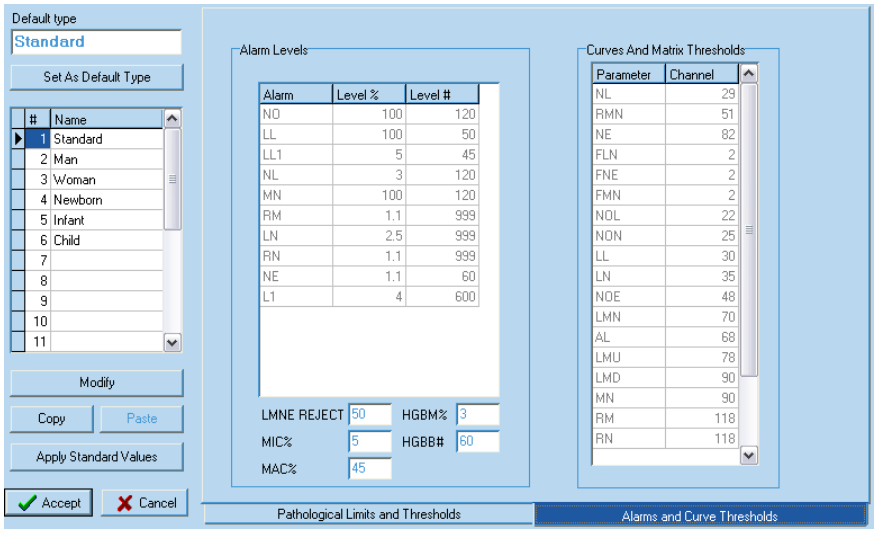
- Define Alarms levels of a blood type.
- Adjust thresholds of the LMNE Matrix and histograms of a blood type.

Access: ***Setting*** > ***Type parametering*** > ***Alarms and Curves Thresholds (tab)***

You have already defined a new type or you want to modify an existing one.

Each flag is adjustable according to a percentage and an absolute value. Flags are triggered off according to these values (see *Workflow* > *Results Interpretation* chapter).

1. Select the type you want to modify in the list.



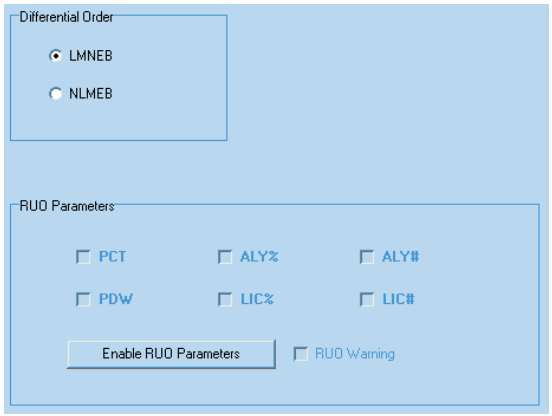
2. Click **Modify**.
3. Enter the password and change the value in the ***Alarms levels*** or ***Curves And Matrix Thresholds*** table.
4. Click **Accept** to validate.

1.3. Parameters

- Define differential order.
- Disable / enable RUO parameters.

Access: ***Setting*** > ***Parameters***

Results differential order can be set either to LMNEB or NLMEB.
RUO Parameters* can be enabled or disabled when data is printed or transmitted. Select **RUO Warning** option if you want to generate a warning on these parameters.



* PDW, PCT, ALY#, ALY%, LIC#, LIC% have not been established as indications for use in United States for this instrument. Their use should be restricted to Research Use Only (RUO). Not for use in diagnostic procedure.

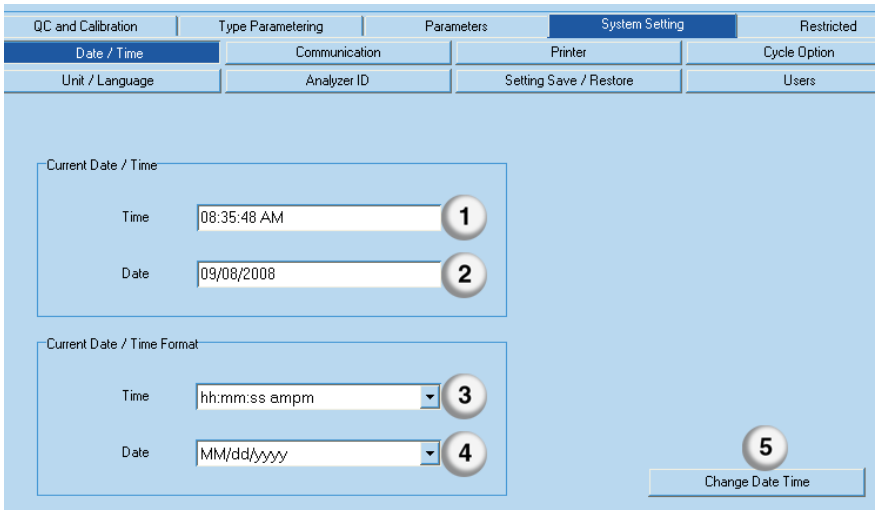
1.4. System Settings

- Set date and time.
- Define RS232C output format and communication protocol.
- Set printing options.
- Define instrument's automatic cleaning frequency and daily workload.
- Define unit set and language.
- Define database maximum capacity.
- Save or restore analyzer and workstation settings.
- Manage user accounts

1.4.1. Date and Time

Adjust date and time according to your country specifications.

Access: ***Setting*** > ***System Setting*** > ***Date and Time (tab)***



1 = Current Time

2 = Current Date

3 = Four types of format can be defined for time:

- hh:mm:ss ampm = from 00 to 12

- h:mm:ss ampm = from 0 to 12
- H:mm:ss = from 0 to 24
- HH:mm:ss = from 00 to 24

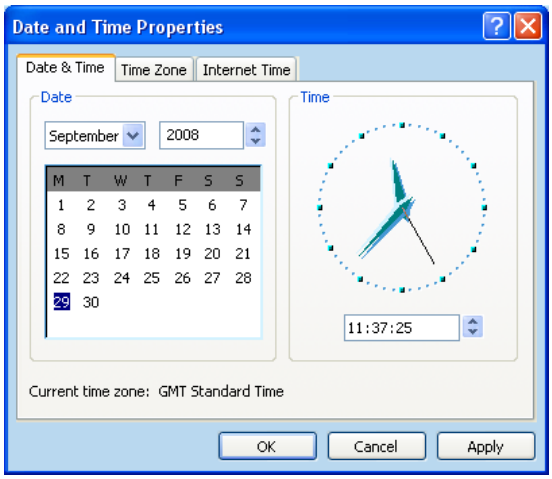
H stands for Hour, **m** for minute and **s** for second.

4 = Three types of format can be defined for date:

- dd/MM/yyyy
- MM/dd/yyyy
- yyyy/MM/dd

d stands for day, **M** for Month and **y** for year.

Click **Change Date Time (5)** to open the ***Date and Time Properties*** window:



Adjust the date and time and click **OK** to validate.

1.4.2. Communication

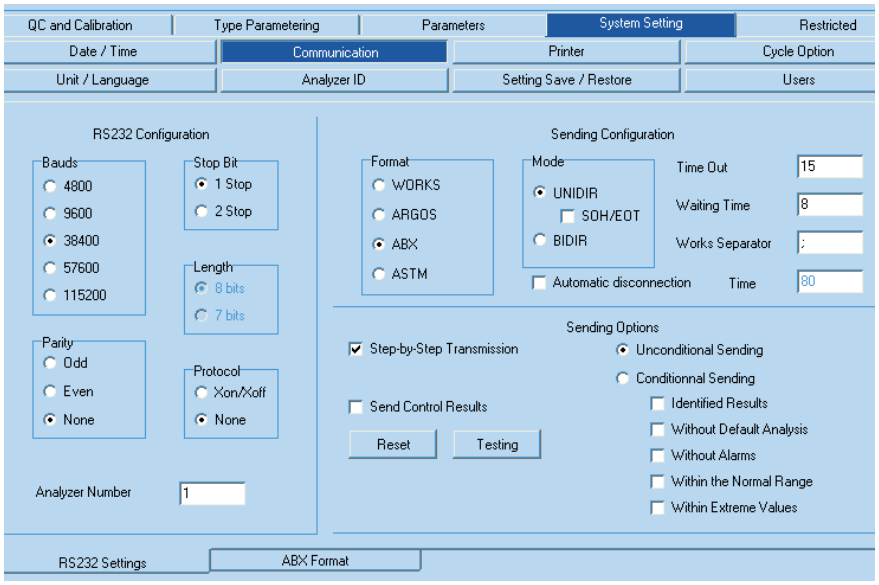
- Set RS232 and sending configuration (ABX and ASTM formats)
- Define ABX Format transmitted data.

Access: ***Setting*** > ***System Setting*** > ***Communication (tab)***

Any modification of the instrument communication setup has to be done in agreement with the technician in charge of the Laboratory Information System (L.I.S.). Information about communication setup of Pentra ES 60 is provided in the *Output Format* documentation.

If any doubt, please contact your local representative.

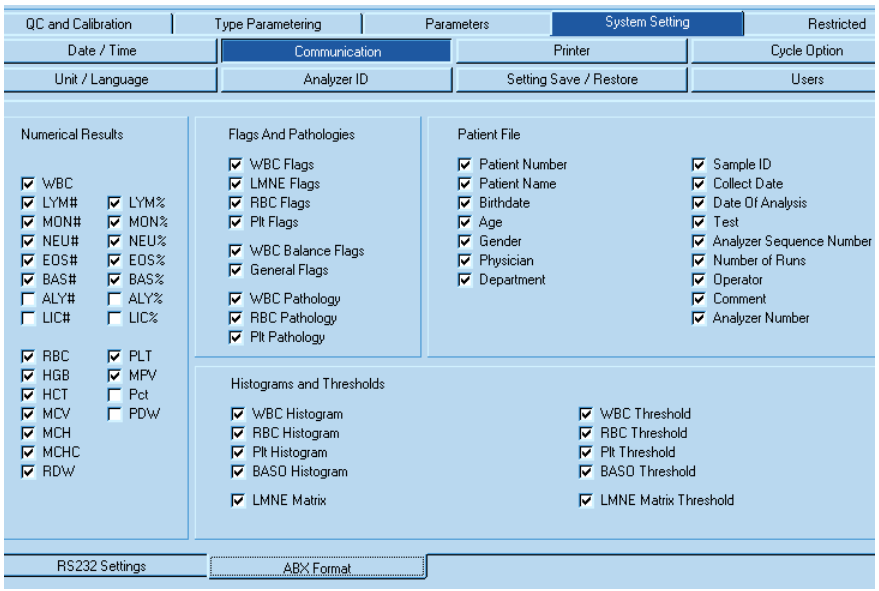
RS232 Settings



- **Reset** sets to zero the communication between workstation and instrument. The results waiting for transmission are erased and line can transmit or receive normally.
- **Testing** performs a serial port connection assay with LIS (only for ABX and ASTM protocols) with current configuration: takes and frees the line. Messages indicate whether the communication is working correctly or not.

ABX Format

Selected items are transmitted:



1.4.3. Printer

- Create or delete a printer.
- Set a default printer.
- Define printout header.
- Define printing options.

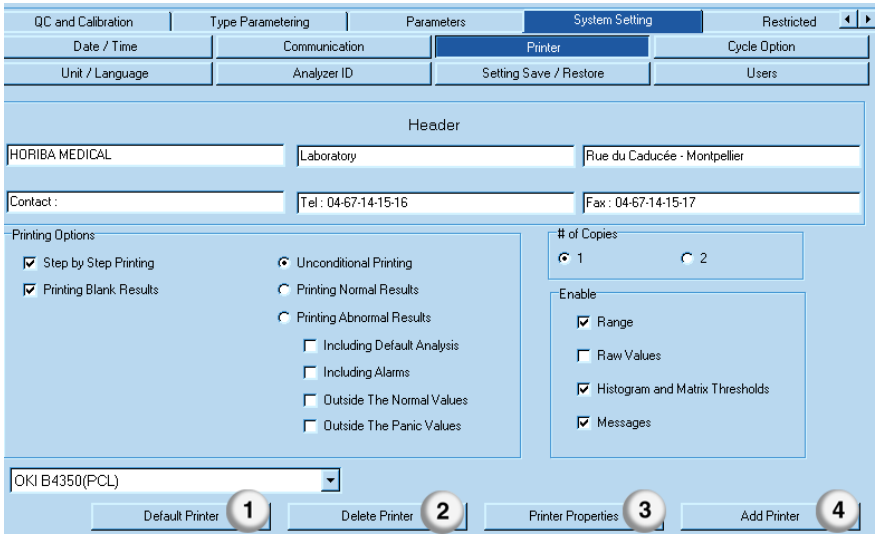
*Access: **Setting** > **System Setting** > **Printer (tab)***

Header

Each printout includes header in two lines that can be defined in the six ***Header*** fields.

Printing options

Options	Action
Step by Step Printing	Select to automatically print results after each analysis cycle
Printing Blank Results	Select to print results on blank cycles (cycles on diluent during startup)
Unconditional Printing	Select to print all the results
Printing Normal Results	Select to print only results within normal ranges, with no alarm nor analysis reject
Printing Abnormal Results	Select to print abnormal results (depending on options selected): ■ with default analysis ■ with alarms ■ out of normal values ■ out of panic values
# of copies	Select to have one or two printouts each time a result is printed out
Enable	■ Select **Range** to print normality ranges on patient results. ■ Select **Raw Values** to print them. ■ Select **Histogram and Matrix Thresholds** to print thresholds in histograms and in the LMNE matrix. ■ Select **Messages** to print pathological messages.



Set as default printer

1. Select a printer from the list.

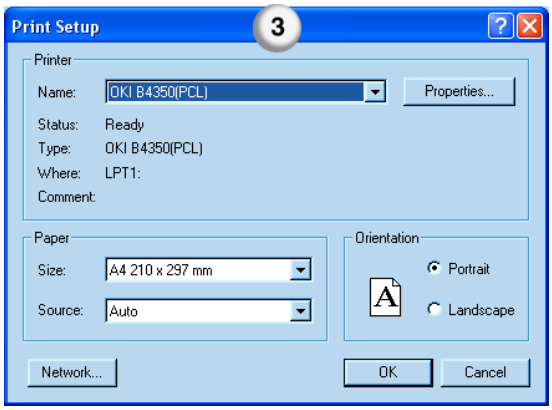
2. Click **Default Printer** (**1**).

Delete a printer

1. Select a printer from the list.
2. Click **Delete Printer** (**2**).

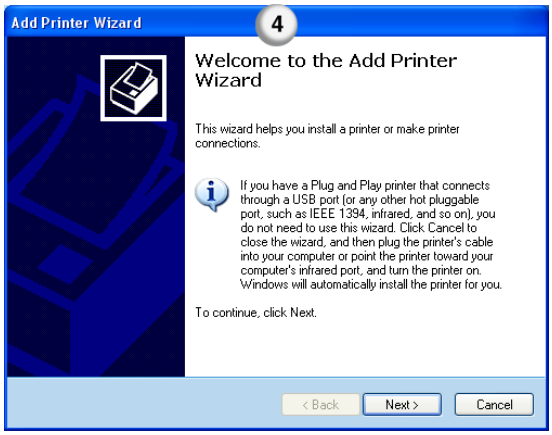
Display printer properties

1. Select a printer from the list.
2. Click **Printer Properties** (**3**) to display the ***Print Setup*** dialog box:



Add a printer

1. Click **Add Printer** (**4**) to display the ***Add Printer Wizard*** window:



2. Follow the instructions. They will guide you through the new printer installation.

1.4.4. Cycle Option

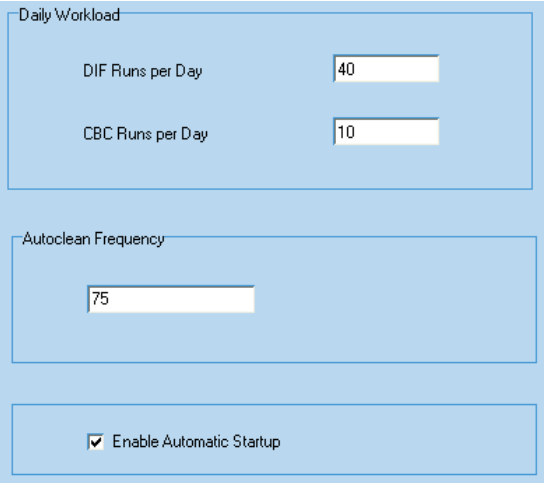
- Set approximate number of CBC and DIF runs per day.
- Set a frequency for autocleaning.
- Enable automatic startup.

Access: ***Setting*** > ***System Setting*** > ***Cycle Option (tab)***

Daily workload: approximate number of DIF and CBC runs per day (used to warn the operator if reagent level is too short for the working day).

Autoclean Frequency: number of analyses performed to trigger an autoclean cycle.

Select the **Enable Automatic Startup** option if you want the analyzer to automatically launch a Startup at the beginning of the day.



See also:
- To Schedule an Automatic Startup, p.79

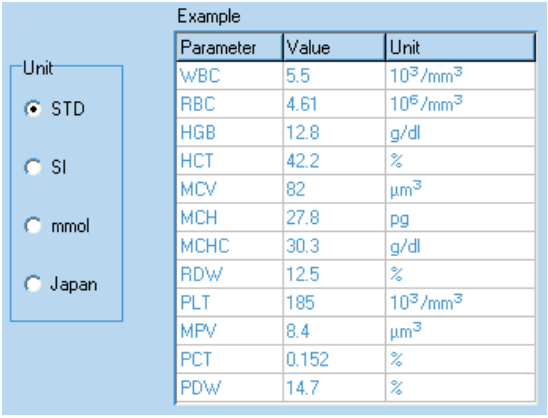
1.4.5. Units and Language

- Define the Units set.
- Set the software language.
- Set the keyboard properties.

Access: ***Setting*** > ***System Setting*** > ***Unit / Language (tab)***

Unit

Select the unit system you want to use:
More information about units in *Specifications* > *Technical Specifications* > *Units* chapter.



Language Options

Select the language you want to use
Click **Close** to confirm. The Workstation is shut down when configuration is changed.
Keyboard Properties: reserved to HORIBA Medical technicians.

See also:
- Units, p.26

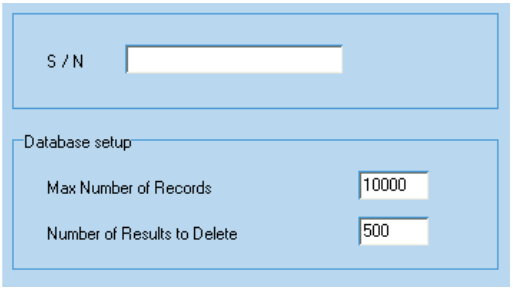
1.4.6. Analyzer ID

- Enter the instrument Serial Number in the workstation software.
- Choose maximum number of records in database.
- Choose number of records to delete in database.

*Access: **Setting** > **System Setting** > **Analyzer ID (tab)***

S/N is the Serial Number of the instrument.

In the ***Database setup*** area, **Max Number of Records** is the maximum number of records that can be stored in the database (from 5000 to 10000). Once this number is reached, the number of records to delete can be set in the **Number of Results to Delete** field (from 500 to 1000).



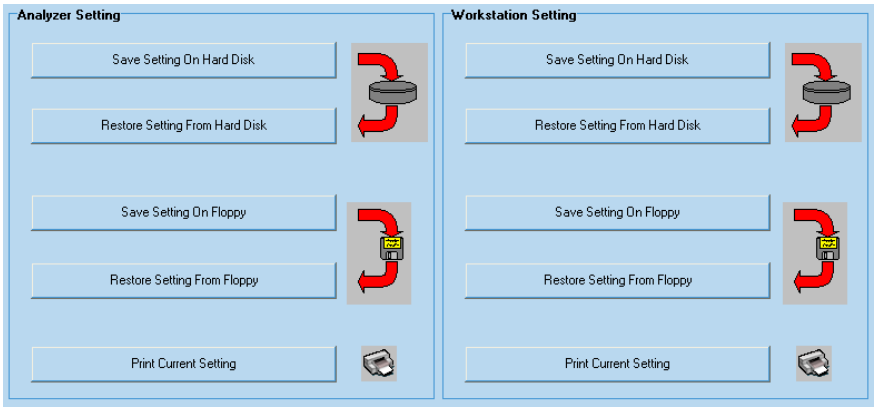
1.4.7. Setting Save / Restore

- Save analyzer or workstation settings on hard disk / floppy drive.
- Restore saved settings on the analyzer and workstation.

*Access: **Setting** > **System Setting** > **Setting Save / Restore (tab)***

Restoring settings do not impact current users accounts (users which have been deleted cannot be restored).

To have a report of your current settings before saving or restoring, click **Print Current Setting**.

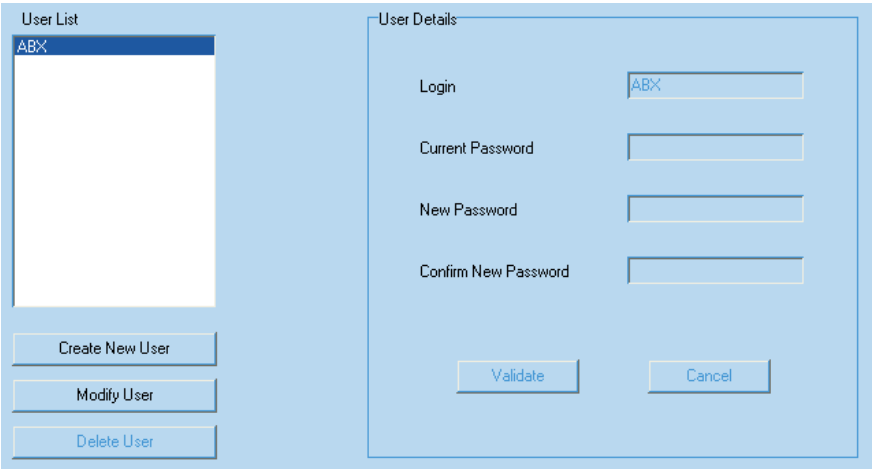


1.4.8. Users

Create, modify or delete a user account.

*Access: **Setting** > **System Setting** > **Users (tab)***

To make the ***User Details*** fields active, click **Create New User** or **Modify User** (for a selected one).
Delete User deletes the selected user, entering its password.



- The maximum length is three characters for Login, and seven characters for Password.
- «ABX» user account can be modified but cannot be deleted.

1.5. Restricted

These settings are restricted to HORIBA Medical technicians.

2. Database

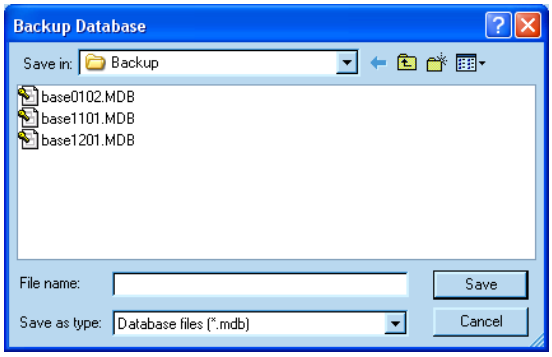
2.1. To Save Database

Save the current instrument database on hard disk.

Access: ***File*** > ***Backup Database***

It is recommended to save your database regularly to secure data.

1. Open the ***Backup Database*** window.
2. Type in a file name and click **Save** to start backup.



When the backup is over, a message is displayed to confirm it.

In order not to exceed the hard drive capacity, it is recommended to use the same file name for every backup (previous backup is then overwritten). Contact your HORIBA Medical representative service department if the hard drive capacity is exceeded.
Backup duration: from 1 to 30 minutes depending on the database weight. To get a quick saving, a weekly backup is recommended.

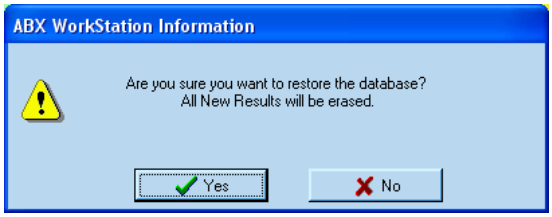
2.2. To Restore Database

Restore a previously saved database on the Workstation.

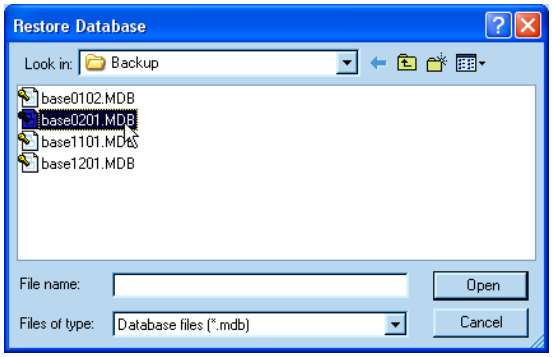
*Access: **File** > **Restore Database***

Data that have not been saved since the last database backup is lost when a database is restored.

1. Open the ***Restore Database*** menu.
   The following message is displayed:



2. Click **Yes** to confirm.
   The ***Restore Database*** window is displayed:



This access is protected by a password. Enter **421** and click **OK** to validate.

3. Choose a database that has previously been saved, and click **Open** to restore it.
   When restoration is over, a message appears and the workstation is restarted.

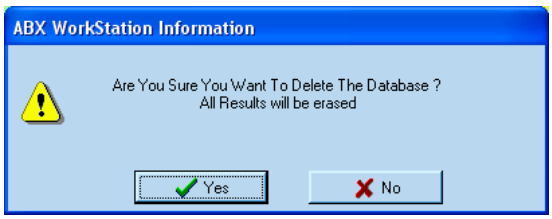
2.3. To Delete Database

Erase all the results and worklists of the current database.

Access: ***File*** > ***Delete Database***

This access is protected by a password. Enter **421** and click **OK** to validate.

1. Select the **Delete Database** menu.
   The ***ABX Workstation Information*** window is displayed:



2. Click **Yes** to confirm deletion.
   When deletion is completed, a message is displayed and the workstation is restarted.

3. Instrument Default Settings

The following values are the software default values for pathological limits and thresholds, alarm levels, and LMNE matrix thresholds. They are classified by types (standard, man, woman, child 1, child 2 and child 3).

3.1. Pathological Limits and Thresholds

Standard:

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	3.80	6.50	6.50
HGB	9.50	11.5	17.0	18.0
HCT	34.0	37.0	54.0	54.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU#	1.70	2.00	7.50	8.0
LYM#	1.00	1.00	4.00	5.00
MON#	0	0.20	1.00	1.50
EOS#	0	0	0.50	0.70
BAS#	0	0	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Man:

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	3.80	6.50	6.50
HGB	9.50	11.5	17.0	18.0
HCT	34.0	37.0	54.0	54.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU#	1.70	2.00	7.50	8.0
LYM#	1.00	1.00	4.00	5.00
MON#	0	0.20	1.00	1.50
EOS#	0	0	0.50	0.70
BAS#	0	0	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Woman:

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	3.00	4.00	10.00	13.00
RBC	3.50	3.80	5.80	6.00
HGB	9.50	11.5	16.0	17.0
HCT	34.0	37.0	47.0	50.0
MCV	70	80	100	110
MCH	25.0	27.0	32.0	34.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	100	150	500	550
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9

Parameter	Panic L	Normal l	Normal h	Panic H
BAS%	0	0	99.9	99.9
NEU#	1.70	2.00	7.50	8.0
LYM#	1.00	1.00	4.00	5.00
MON#	0	0.20	1.00	1.50
EOS#	0	0	0.50	0.70
BAS#	0	0	0.20	0.25
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

Child 1 (from 1 day to 6 month old):

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	10.0	10.0	26.0	30.0
RBC	4.00	4.00	6.00	6.00
HGB	13.5	13.5	19.5	19.5
HCT	44.0	44.0	64.0	64.0
MCV	98	100	112	114
MCH	30.0	30.0	38.0	38.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU#	6.00	6.00	26.0	26.0
LYM#	2.00	2.00	11.0	11.0
MON#	0.40	0.40	3.10	3.10
EOS#	0	0	0.85	0.85
BAS#	0	0	0.65	0.65
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.35	0.35
LIC#	0	0	0.35	0.35

Child 2 (from 6 month to 2 years old):

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	10.0	10.0	26.0	30.0
RBC	4.00	4.00	6.00	6.00
HGB	13.5	13.5	19.5	19.5
HCT	44.0	44.0	64.0	64.0

Parameter	Panic L	Normal l	Normal h	Panic H
MCV	98	100	112	114
MCH	30.0	30.0	38.0	38.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU#	6.00	6.00	26.0	26.0
LYM#	2.00	2.00	11.0	11.0
MON#	0.40	0.40	3.10	3.10
EOS#	0	0	0.85	0.85
BAS#	0	0	0.65	0.65
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.35	0.35
LIC#	0	0	0.35	0.35

Child 3 (from 2 years to 14 years old):

Parameter	Panic L	Normal l	Normal h	Panic H
WBC	4.50	4.50	13.5	15.0
RBC	4.00	4.00	5.40	5.40
HGB	11.0	11.5	14.5	15.0
HCT	37.0	37.0	45.0	45.0
MCV	75	77	91	93
MCH	24.0	24.0	30.0	30.0
MCHC	32.0	32.0	36.0	36.0
RDW	10.0	11.0	16.0	17.0
PLT	150	200	400	450
MPV	6	6	11	12
PCT	0	0.15	0.50	1.00
PDW	7	11	18	20
NEU%	0	0	99.9	99.9
LYM%	0	0	99.9	99.9
MON%	0	0	99.9	99.9
EOS%	0	0	99.9	99.9
BAS%	0	0	99.9	99.9
NEU#	1.80	1.80	8.00	8.00
LYM#	1.50	1.50	6.50	6.50
MON#	0	0	0.8	0.8
EOS#	0	0	0.60	0.60

Parameter	Panic L	Normal l	Normal h	Panic H
BAS#	0	0	0.20	0.30
ALY%	0	0	2.5	2.5
LIC%	0	0	3.0	3.0
ALY#	0	0	0.25	0.25
LIC#	0	0	0.30	0.30

3.2. Alarms Levels

Standard:

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	
HGB	3	60

Man:

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	

Alarm	Level%	Level#
HGB	3	60

Woman:

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	
HGB	3	60

Child 1 (from 1 day to 1 month old):

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	
HGB	3	60

Child 2 (from 1 month to 2 years old):

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120

Alarm	Level%	Level#
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	
HGB	3	60

Child 3 (from 2 years to 14 years old):

Alarm	Level%	Level#
NO	100	80
LL	100	80
LL1	5	55
NL	3	120
MN	15	120
RM	0.7	999
LN	2.5	999
RN	1.1	999
NE	1.1	30
L1	3	200
LMNE reject	50	
MIC	5	
MAC	45	
HGB	3	60

3.3. Matrix Thresholds

Standard:

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78

Matrix thresholds	Channel	
	Proposed	Current
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Man:

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Woman:

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30

Matrix thresholds	Channel	
	Proposed	Current
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Child 1 (from 1 day to 1 month old):

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Child 2 (from 1 month to 2 years old):

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35
BA2	110	110
BA3	240	240

Child 3 (from 2 years to 14 years old):

Matrix thresholds	Channel	
	Proposed	Current
NOL	24	22
NON	27	25
LL	31	30
LN	35	35
NOE	50	48
LMN	69	70
AL	69	68
LMU	73	78
LMD	100	90
MN	100	90
RM	118	118
RN	118	118
NL	29	29
RMN	51	51
NE	82	82
FLN	2	2
FNE	2	2
FMN	2	2
BA1	35	35

Matrix thresholds	Channel	
	Proposed	Current
BA2	110	110
BA3	240	240

3.4. QC Variation Coefficients

Parameter	Max CV
WBC	5
RBC	5
HGB	3
HCT	5
MCV	3
MCH	3
MCHC	3
RDW	10
PLT	10
MPV	10
NEU%	10
LYM%	10
MON%	35
EOS%	15
BAS%	10
NEU	10
LYM	10
MON	35
EOS	15
BAS	10

3.5. XB Limits

Parameter	Value	Tolerance
WBC	7	3
RBC	5	1
HGB	14	3
HCT	45	5
PLT	320	100
MCV	90	10
MCH	29	2
MCHC	34	2

Parameter	Value	Tolerance
RDW	14	2

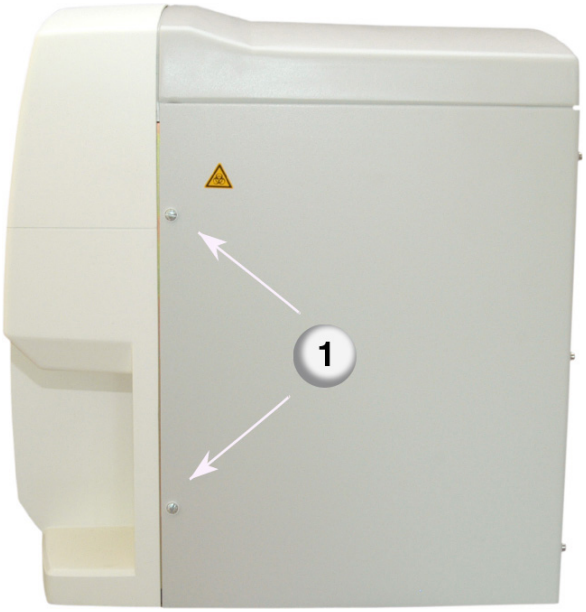
Maintenance and Troubleshooting

1. Maintenance

1.1. To Remove Instrument Covers

Open the right, left and top covers of the instrument.

1. In ***Service*** > ***Mechanical Systems*** > ***Maintenance Carriage Position (tab)*** , click **Run** to place the carriage in a maintenance position.
2. Switch off the instrument and disconnect the power supply cable.
3. Unscrew the two screws (**1**) of the right door with a flat screwdriver.



4. Open the pneumatic access door.

5. Unscrew the four left cover screws (**2**) with a hexagonal key. Remove the left cover.

Use the hexagonal keys supplied in the installation kit.

6. Unscrew the main board tightening screws (**3**) to open the board support panel.

Be careful not to disconnect the flat cables while opening the board support panel.

7. Unscrew the seven hexagonal screws (**4**) of the top cover.

8. Remove the top cover carefully.

Once you have completed the required maintenance or replacement procedure, first place the top cover. Then close the main board panel, and place the left cover. Then close the right door with a flat screwdriver.

See also:
- To Park the Syringes, p.173

1.2. Reagents Replacement

- Replace empty diluent container or empty reagent bottles.
- Prime reagents.
- Replace the waste container.

Verification after a reagent replacement: make sure a blank cycle and a control run have been performed after a reagent replacement during the day.

1.2.1. To Replace the Diluent Container

Replace the empty ABX Diluent container.

Access: ***Main screen*** > ***Analyzer (tab)***

At instrument startup, the remaining quantity of ABX Diluent is compared to the daily workload set up by the user. If a low level is expected during the working day, a dialog box appears. You can click **OK** and go on running specimen until the dialog box appears again. Then, the ABX Diluent must be changed.

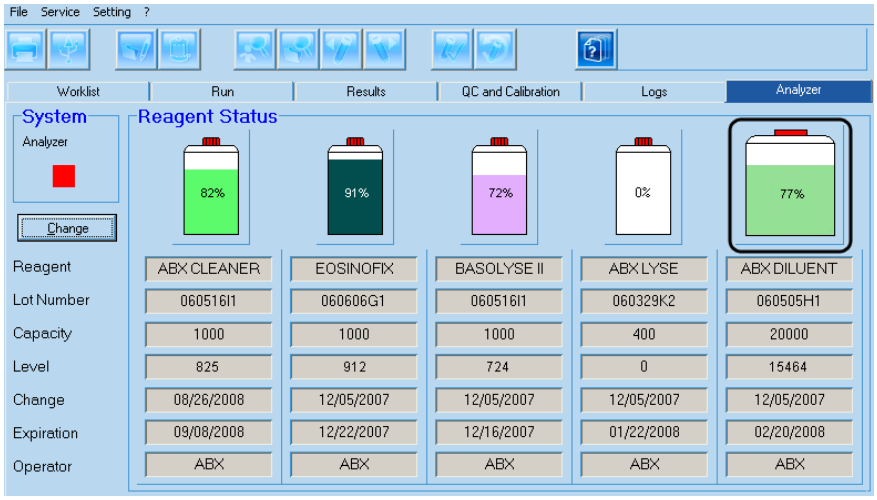
1. Unscrew the stopper assembly of the new container.

   Risk of erroneous results if one reagent is poured to another container. Never pour a reagent from one container to another. Particles at the bottom of the old container can contaminate the new reagent and will cause unacceptable background results especially for Platelets.

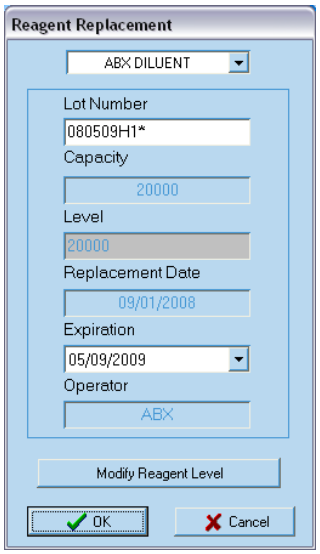
2. Remove the stopper assembly straw from the empty container and insert it into the new one.

   Properly dispose of the empty reagent container. Follow your local regulations for reagent disposal.

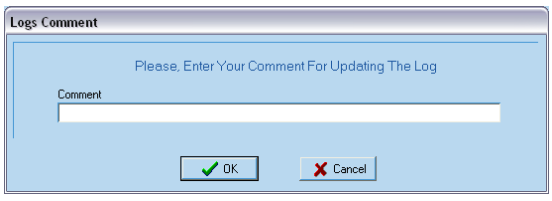
3. In the ***Analyzer*** tab, double-click the ABX Diluent icon.



4. In the ***Reagent Replacement*** dialog box, enter the new Diluent's **Lot Number** (indicated on reagent packaging).



5. Enter the new Diluent's **Expiration** date and click **OK** in the ***Reagent Replacement*** dialog box to save your modifications.
6. In the ***Logs Comment*** dialog box, enter a comment to update the reagents log.



7. Click **OK** to validate.
   A prime cycle is automatically launched by the instrument.

8. When the priming is finished, the ***Analyzer*** tab is updated.

The reagent log has been updated in the ***Logs*** tab.

See also:
- To Replace a Reagent Bottle, p.161
- To Prime Reagents, p.163
- To Replace the Waste Container, p.164
- Reagents Location, p.37
- Reagents Description, p.38
- Reagent Notices, p.39
- Instrument Reagent Consumption, p.39
- Waste Handling Precautions, p.40

1.2.2. To Replace a Reagent Bottle

Replace an empty reagent bottle.

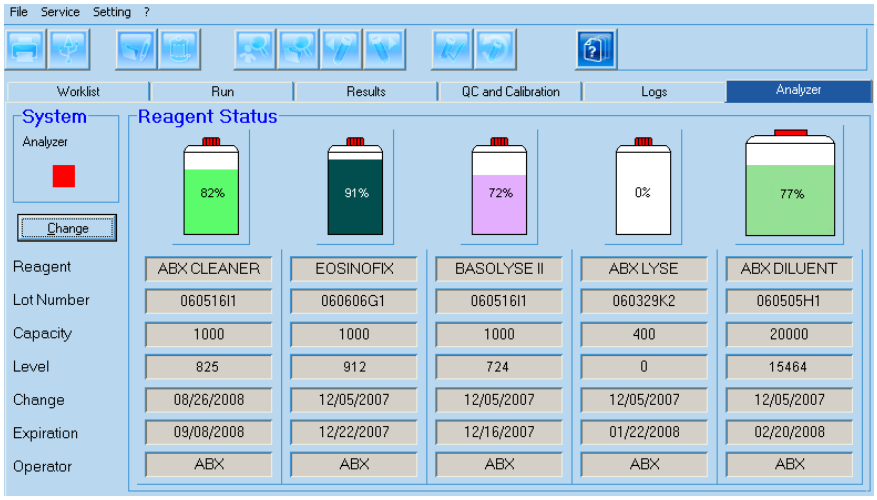
Access: ***Main screen*** *>* ***Analyzer (tab)***

At instrument startup, the remaining quantity of each bottle is compared to the daily workload set up by the user. If a low level is expected during the working day, a dialog box appears. You can click **OK** and go on running specimen until the dialog box appears again. Then, the bottle must be changed.

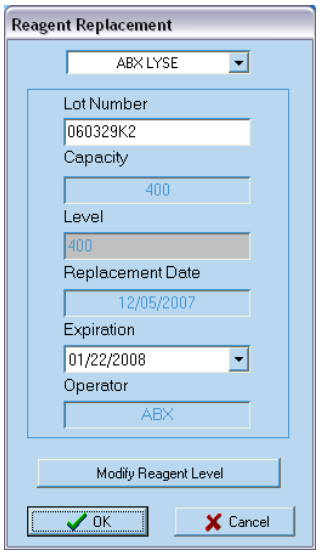
1. Open the front door and remove the empty bottle from the reagent compartment.
2. Uncap a new reagent bottle.
3. Insert the stopper assembly tube into the new bottle and tighten the stopper assembly to ensure an adequate seal.
4. Install this new reagent bottle into the reagent compartment and close the door.

Properly dispose of the empty reagent container. Follow your local regulations for reagent disposal.

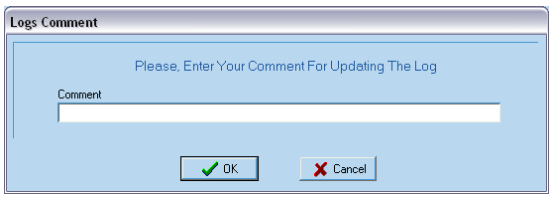
5. In the ***Analyzer*** tab, double-click the reagent bottle icon to replace.



6. In the ***Reagent Replacement*** dialog box, enter the new reagent's **Lot Number** (indicated on reagent packaging).

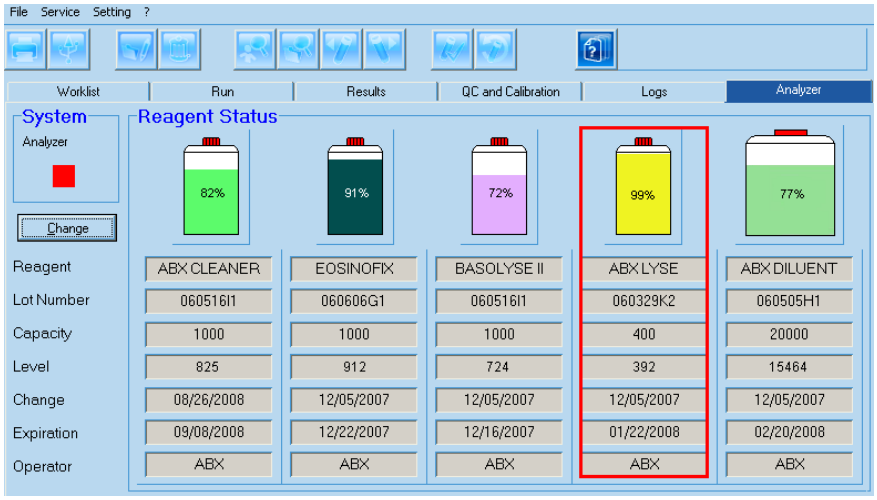


7. Enter the new reagent's **Expiration** date and click **OK** in the ***Reagent Replacement*** dialog box to save your modifications.
8. In the ***Logs Comment*** dialog box, enter a comment to update the reagents log.



9. Click **OK** to validate.
   A prime cycle is automatically launched by the instrument.

10. When the priming is finished, the ***Analyzer*** tab is updated:



The reagent log has been updated in the ***Logs*** tab.

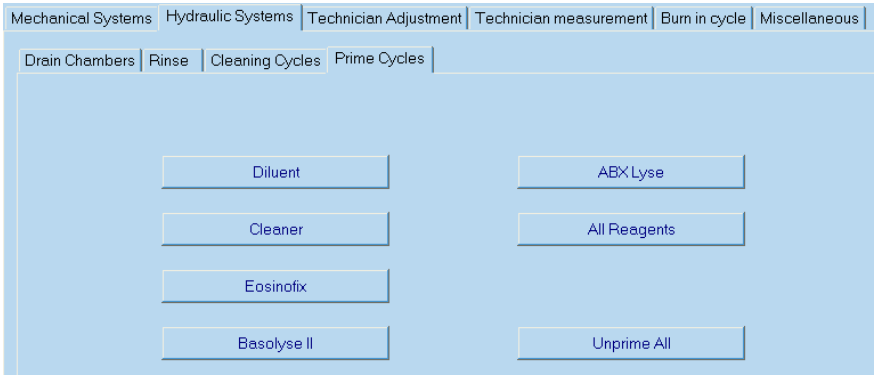
See also:
- To Replace the Diluent Container, p.159
- To Prime Reagents, p.163
- To Replace the Waste Container, p.164
- Reagents Location, p.37
- Reagents Description, p.38
- Reagent Notices, p.39
- Instrument Reagent Consumption, p.39
- Waste Handling Precautions, p.40

1.2.3. To Prime Reagents

- Prime reagents into the instrument.
- Unprime all reagents from the instrument.

Access: ***Service*** > ***Hydraulic Systems*** > ***Prime Cycles (tab)***

Run these cycles to prime reagents into the instrument, after service has been performed or after a reagent replacement for example.



- Click the button corresponding to a reagent to prime it, or click **All Reagents** to prime them all at a time.
- Click **Unprime All** to remove all reagents from the instrument.

See also:
- To Replace the Diluent Container, p.159
- To Replace a Reagent Bottle, p.161
- To Replace the Waste Container, p.164
- Reagents Location, p.37
- Reagents Description, p.38
- Reagent Notices, p.39
- Instrument Reagent Consumption, p.39
- Waste Handling Precautions, p.40

1.3. To Replace the Waste Container

Replace the waste container whenever this one is filled up.

When disposing of waste, protective clothing must be worn (lab coat, gloves, eye protection, etc.). Follow your local and/or national guidelines for biohazard waste disposal.

- At the beginning of each day, before startup, check if the waste container needs to be emptied.
- During instrument operation, do not remove the reagent tubes and the liquid waste tube under any condition.

1. Make sure no cycle is in progress.
2. Unscrew the waste container cap.
3. Screw the cap on the full waste container and follow your local and/or national guidelines for biohazard waste disposal.
4. Close the empty container with the cap.

See also:
- To Check the Waste Container Level, p.74
- Waste Handling Precautions, p.40

1.4. To Decontaminate your Instrument

Clean externally and internally the instrument considering the biological environment.

- Never spill liquid on the instrument.
- Never use disinfectant product* that contains alcohol.

All contaminated surfaces (covers, counting assembly area...)

Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces

Stainless steel parts

Slightly wet a sponge with disinfectant product* and wipe the dirty surfaces. Dry with a soft cloth.

Computer screen

Use a soft clot, slightly wet with disinfectant product*. Wipe gently the screen and dry to remove any trace of moisture.

*Products having the following microbiological properties:

- Bactericidal
- Fungicidal
- Active on Aspergillus fumigatus
- Active on Mycobacterium tuberculosis (B.K)
- Antiviral (VIH, HBV and rotavirus)

Product Example validated by HORIBA Medical: ANIOS detergent disinfectant ; WIP'ANIOS ; ref: 1316.424

See also the W.H.O (World Health Organization) guidelines: «*Laboratory Biosafety Manual, 2nd edition*», for further information.

Instrument internal cleaning

Counting chambers and hydraulics parts are decontaminated by using the «Concentrated cleaning» procedure. See *Hydraulic Maintenance > To Perform a Concentrated Cleaning* chapter.

Sampling probe

Sampling probe must be decontaminated as follows:

1. Prepare a solution of Sodium Hypochlorite to 100ml/l.
2. Fill a 5ml tube with this solution.
3. Run 5 analysis on bleach.

See also:
- To Perform a Concentrated Cleaning, p.167

1.5. Hydraulic Maintenance

Perform the required maintenance cleaning cycles.

1.5.1. Cleaning Frequency

One of the main factor contributing to accurate and reliable results is to have a well-maintained instrument. Several maintenance functions are available for the user to clean and check the instrument. First follow the cycle frequencies indicated in the table below:

Cycles	< 100 analyzes per day	> 100 analyzes per day
Startup	1 per day	1 per day
Shutdown	1 per day	1 per day
Cleaning cycle	automatic after 2 hours standby	automatic after 2 hours standby
Concentrated cleaning	1 per month	2 per month
Sample carriage cleaning	1 per month	1 per month

1.5.2. To Perform a Shutdown

Perform an instrument shutdown before ending your work session.

*Access: **Main screen** > **Shut Down (icon)***

The main screen has to be displayed.

1. Click **Shut Down**:


2. Wait during shutdown cycle.

Once the shutdown is completed, the instrument can be switched off.

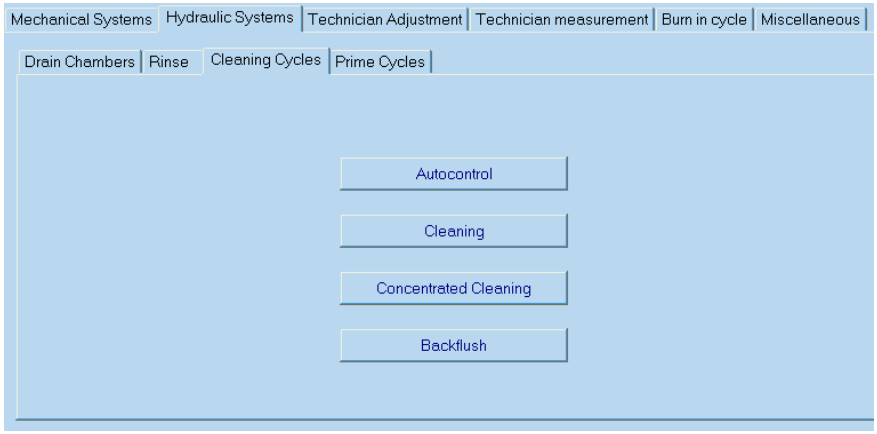
1.5.3. To Perform a Cleaning Cycle

Follow this procedure to run a Cleaning cycle.

Access: ***Service*** > ***Hydraulic Systems*** > ***Cleaning Cycles (tab)***

After two hours off, the system automatically asks the user to run this cycle.

1. In the **Cleaning Cycles** tab, click **Cleaning**.



This cycle performs a chamber rinsing and primes reagent that could remained into the heating coil.

1.5.4. To Perform a Concentrated Cleaning

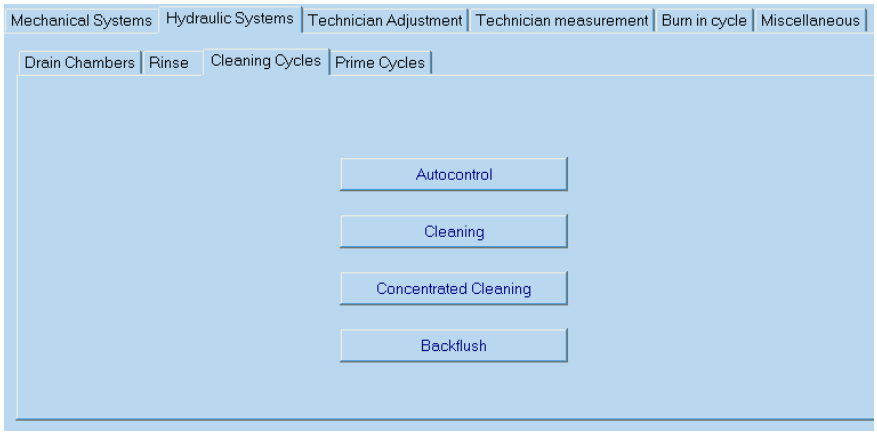
Follow this procedure to give the counting chambers a thorough cleaning in case of a poor repeatabilty, or failed startup.

Access: ***Service*** > ***Hydraulic Systems*** > ***Cleaning Cycles (tab)***

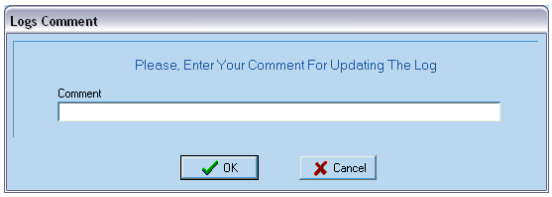
Prepare a 5mL syringe, a bottle brush and ABX Minoclair.

It is highly recommended to use ABX Minoclair for these cleaning operations. Refer to the Material Safety Data Sheet for handling precautions.
Sodium Hypochlorite concentration: 1,3% of active chlorine.
Warning not to use bleach constitued with concentrated tablet.

1. In the ***Cleaning Cycles*** tab, click **Concentrated Cleaning**.



2. Click **OK** to confirm.
3. Add comments in the **Comment** field to update the ***Reagents Logs***:

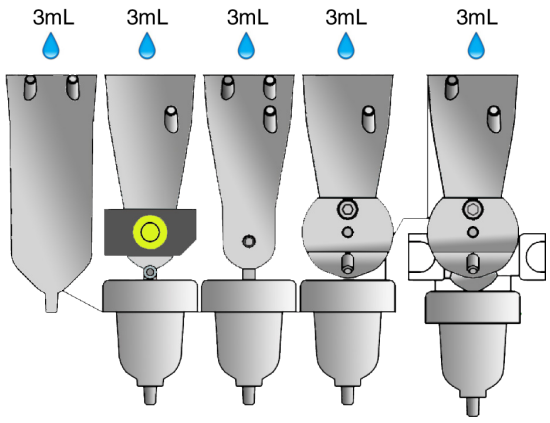


4. When this window is displayed, open the instrument pneumatic door (right side).

Do not click **OK** until you have poured the ABX Minoclair (or diluted bleach) in each chambers.

---

5. Use the syringe to pour 3mL of ABX Minoclair (or diluted bleach) in each chamber.



6. Soak the bottle brush with ABX Minoclair and use it to clean only the upper part of the chambers if needed.
7. Click **OK**.

8. Close the instrument pneumatic door and wait for the instrument to complete the cleaning procedure (about five minutes).
9. When the progression bar is ended, click **OK** to exit the concentrated cleaning cycle.

Run an analysis on a control blood.

See also:
- To Remove Instrument Covers, p.156

1.5.5. To Clean the Sample Carriage

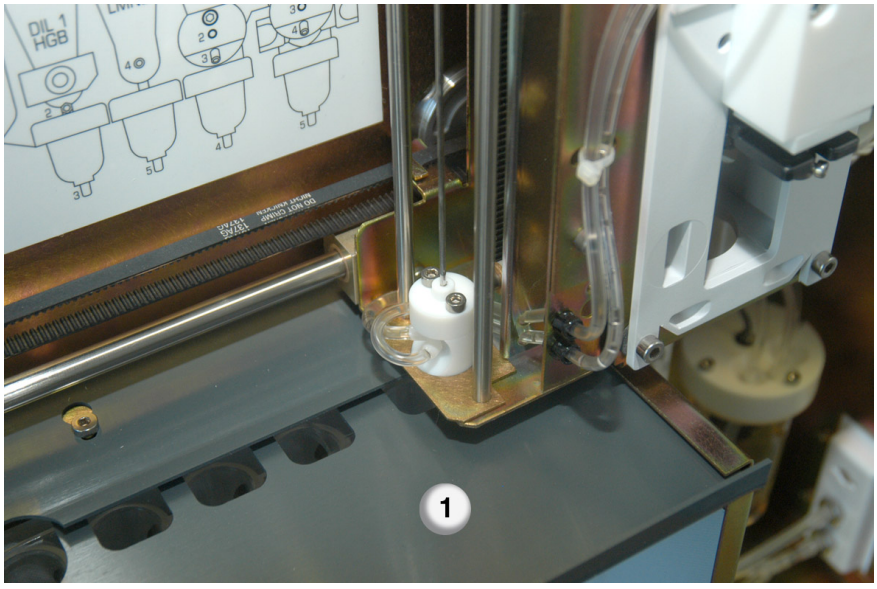
Clean the sample carriage and the chambers covers.

Access: ***Service*** > ***Mechanical Systems*** > ***Maintenance Carriage Position (tab)***

Prepare bottle brush, absorbant paper and ABX Minoclair.

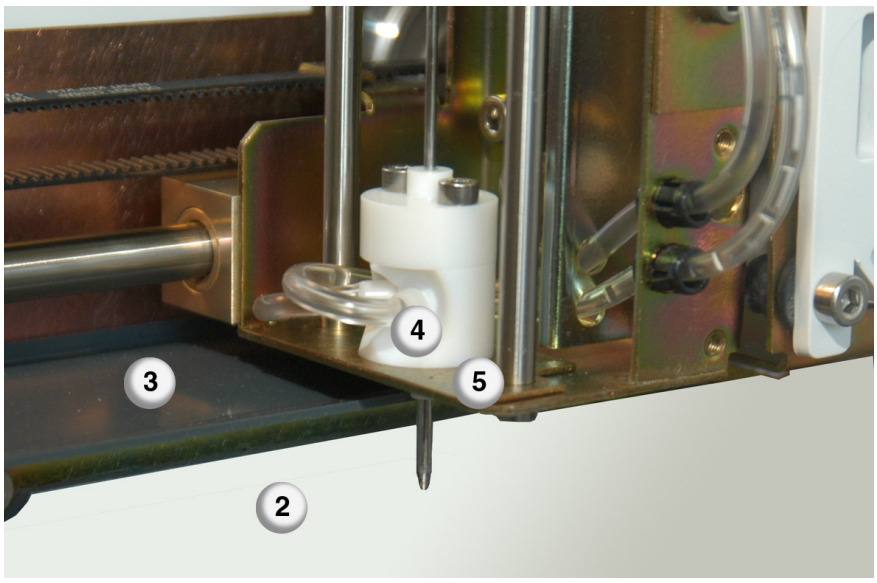
It is highly recommended to use ABX Minoclair for these cleaning operations. Refer to the Material Safety Data Sheet for handling precautions.
Sodium Hypochlorite concentration: 1,3% of active chlorine.
Warning not to use bleach constitued with concentrated tablet.

1. Click Run in the ***Maintenance Carriage Position*** tab.
2. Open the instrument pneumatic door (refer to *Maintenance* > *To Remove Instrument Covers* chapter).
3. Clean the upper surface of the chambers cover (1) with wet absorbant paper.



While cleaning under the carriage, small elements can drop into the chambers.

4. Put a sheet of paper (2) on the chambers cover (1):



5. Clean the protection (3) with wet absorbant paper.
6. Use the bottle brush soaked with bleach to clean the white assembly (4) and below the carriage support panel (5).
7. Remove and dispose of the sheet of paper (2).
8. Close the instrument pneumatic door.
9. Click **OK** to move the carriage back to its initial position.

See also:
- To Remove Instrument Covers, p.156

1.6. Mechanical Systems Menu

- Reset instrument
- Check motors
- Check valves
- Position carriage for maintenance
- Position syringes for storage

1.6.1. To Initialize Mechanical & Hydraulical Assemblies

Run an initialization to reset mechanical and hydraulic assemblies

Access: ***Service*** > ***Mechanical Systems*** > ***Initialization (tab)***

After an initialization, all the mechanical assemblies (sampling needle, carriages, syringes, etc) return to their initial position, which is the operating analysis position. To initialize the instrument, click **Run**.

A progression bar is displayed. Wait until it stops before doing any other action.

1.6.2. To Check Motors

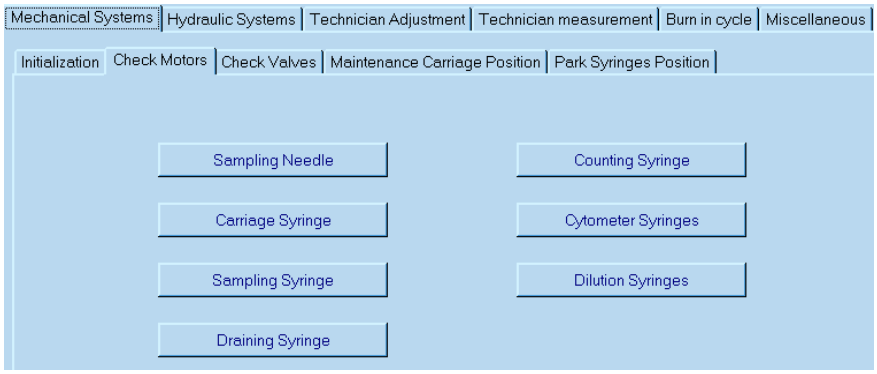
Control the correct operation of each motor.

Access: ***Service*** > ***Mechanical Systems*** > ***Check Motors (tab)***

1. Switch off the instrument.
2. Open both the right cover and the left cover of the instrument.
3. Loosen the two screws of the board support panel and open it.

Be careful not to disconnect the flat cables while opening the board support panel.

4. Switch on the instrument.
5. In the ***Check Motors*** tab, click the button corresponding to a motor:



- **Sampling Needle**: check the needle up and down operations. The movements should be smooth and regular.
- **Carriage Syringe**: check the right and left movements of the carriage.
- **Sampling Syringe**: check the smooth and complete movement of the syringe.
- **Draining Syringe**: check the smooth and complete movement of the syringe.
- **Counting Syringe**: check the smooth and complete movement of the syringe.
- **Cytometer Syringes**: check the smooth and complete movement of the syringes.
- **Dilution Syringes**: check the smooth and complete movement of the syringes.
- **Piercing Mechanism**.

See also:
- To Remove Instrument Covers, p.156

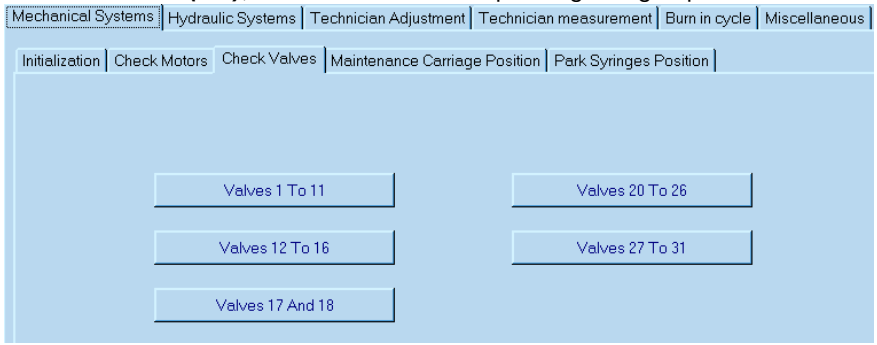
1.6.3. To Check Valves

Control the correct operation of each valve.

Access: ***Service*** > ***Mechanical Systems*** > ***Check Valves (tab)***

To control the operation of a valve:

1. Open both the right cover and the left cover of the instrument.
2. In ***Check Valves (tab)***, click the button corresponding to a group of valves:



3. Observe the valve operations carefully: the movements have to be straight and regular.

See also:
■ To Remove Instrument Covers, p.156

1.6.4. To Move the Carriage to a Maintenance Position

Get an easy access to carriage assembly during a maintenance.

Access: ***Service*** > ***Mechanical Systems*** > ***Maintenance Carriage Position***

This function allows the user to automatically move the sample carriage over the chamber area to simplify maintenance operations such as the replacement of a sampling needle or other maintenance procedures that may require the movement of the sample carriage.

1. Click **Run** to move the carriage to its maintenance position.

   A progression bar is displayed. Wait until it stops before doing any other action.

2. Once maintenance is done, click **OK** to let the carriage return to its initial position.

1.6.5. To Park the Syringes

Park the instrument syringes for storage or transportation.

Access: ***Service*** > ***Mechanical Systems*** > ***Park Syringes Position (tab)***

This function parks syringes when the instrument is not used for a long time or for transportation. Click **Run** to park intrument syringes.

A progression bar is displayed. Wait until it stops before doing any other action.

1.7. Hydraulic Systems Menu

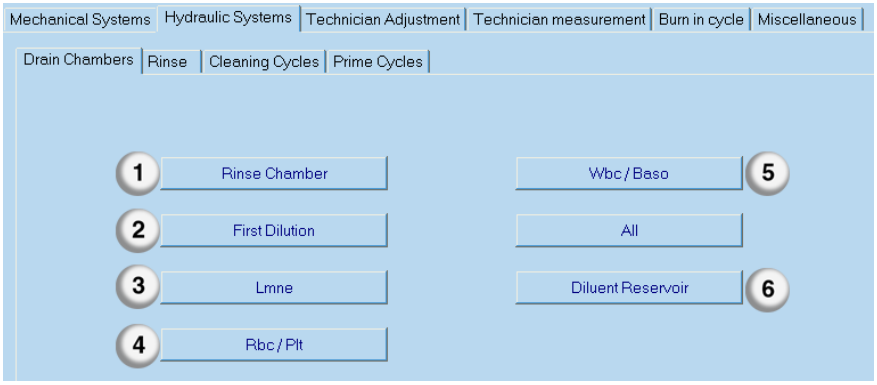
- Drain the instrument chambers.
- Run rinsing cycles.
- Run cleaning cycles.
- Prime reagents.

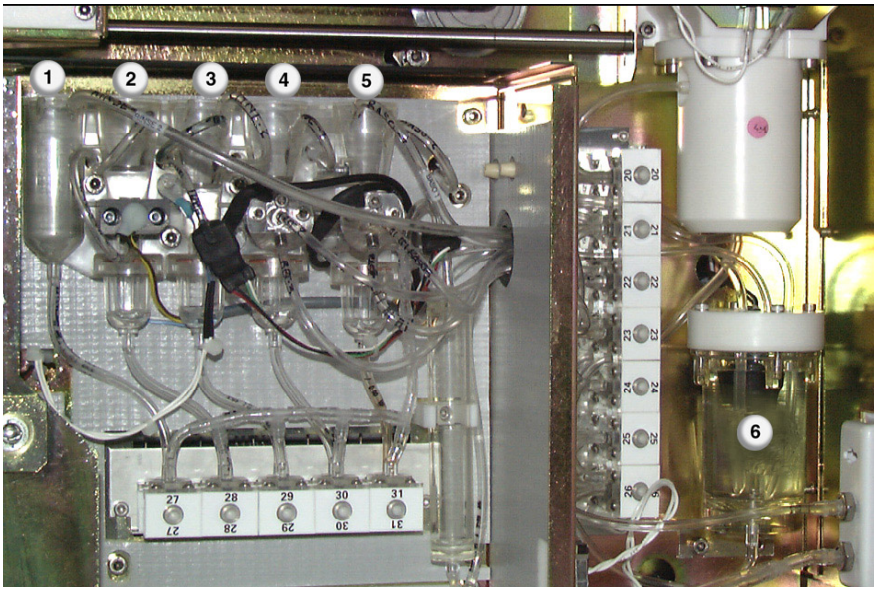
1.7.1. To Drain Chambers

Drain the 5 instrument chambers and/or the diluent reservoir.

Access: ***Service*** > ***Hydraulic Systems*** > ***Drain Chambers (tab)***

You can drain chambers if you detect a problem with the instrument's chambers.





Run an autocontrol to prime reagents in the chambers that have been drained.

1.7.2. To Rinse Chambers and Cytometer

- Rinse the instrument chambers.
- Rinse the instrument cytometer.

Access: ***Service*** > ***Hydraulic Systems*** > ***Rinse (tab)***

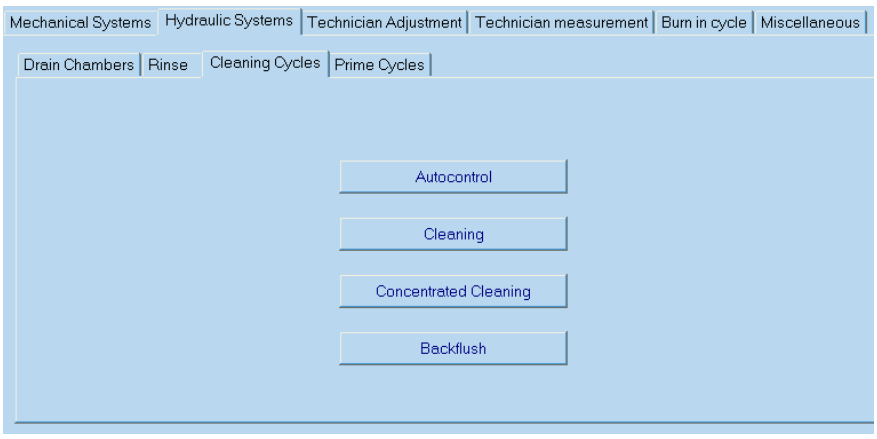
You can either:

- **Rinse Chambers**, if you have excessive flagging on CBC parameters.
- **Rinse Cytometer**, to remove bubbles from the flowcell if you have excessive flagging on 5DIFF parameters.

1.7.3. Cleaning Cycles

Launch cycles to clean the instrument.

Access: ***Service*** > ***Hydraulic Systems*** > ***Cleaning Cycles (tab)***



Autocontrol cycle

A series of mechanical, hydraulic and electronic networks control is performed:

- General rinsing
- Control of the correct draining of chambers
- Initialization of mechanical assemblies

Cleaning cycle

This cycle performs a chamber rinsing and primes reagent that could remained into the heating coil.

After two hours off, the system automatically asks the user to run this cycle.

Concentrated Cleaning cycle

This cycle has to be done to clean the chambers with bleach. To perform a concentrated cleaning, see *Maintenance* > *Hydraulic Maintenance* chapter.

Backflush cycle

This cycle delivers pressure through the rear of the apertures to remove blockages. Do this procedure if you suspect the apertures are blocked.

See also:
- To Perform a Concentrated Cleaning, p.167

2. Troubleshooting Procedures

Whatever the issue occuring on your instrument, a series of controls can be performed in the following logical order before attempting to carry out any intervention:

1. Is there an instrument or peripheral operating issue? If obviously no doubt can be made on the system operation, step to following question. If there is a possible issue on this, please check the user manual corresponding procedures.
2. Are there mechanical, sampling or dilution problems while analysis cycle is running? If obviously no doubt can be made on the analysis cycle operations, step to following question. If there is a possible issue on this, please check the user manual corresponding procedures.
3. Are there incorrect results on all parameters or several only? If obviously no doubt can be made on the results given by the instrument, step to following question. If there is a possible issue on this, please check the user manual corresponding procedures
4. Are there lots of flags, pathology messages or technical alarms? If there is a possible issue on the alarms given by the instrument, please check the user manual corresponding procedures

See also:
- Operation Problems, p.177
- Analysis Cycle Problems, p.180
- Results Problems, p.183

2.1. Operation Problems

- Verify peripherals and instrument operations.
- Control your reagents.
- Run a startup to check the correct operations.

2.1.1. Workstation Power Problems

Follow this procedure if you have problems starting the Workstation.

1. Make sure the power cord is connected properly. See computer's user manual to connect it.
2. Try to restart the Workstation.

If nothing happens, please contact your local HORIBA Medical representative.

2.1.2. Workstation Login Problem

Follow this procedure if you have problems logging in the Workstation application.

1. Log in with "ABX" account (no password is needed).
   If you cannot log in with "ABX" login, please contact your local HORIBA Medical representative.
2. If the application starts, verify that your account is in the ***Setting*** > ***System Setting*** > ***Users*** menu.
3. If your account is not in the list, create a new user account.

See also:
- Users, p.138

2.1.3. Workstation Communication Problem

Follow this procedure if the Workstation cannot communicate with the instrument.

You cannot run any cycle from the Workstation application.

1. Verify the connection to the instrument (Instrument RS232 output to Workstation).
   See *Introduction* > *Peripherals Connections* chapter.
2. Verify that the instrument is switched on.
3. Try to run an **Autocontrol** cycle.
   If you still cannot run any cycle, please contact your local HORIBA Medical representative.

2.1.4. Printer Operation Problems

Follow this procedure if the printer does not work.

1. Check that the printer power cord is connected properly.
2. Switch off and on the printer.

3. Check the paper feed.
4. Refer to your printer's user manual.
5. Check the printer's configuration in ***Setting*** > ***System Setting*** > ***Printer*** menu.
   If all these operations appear to be correct and that the system still does not work properly, please contact your local HORIBA Medical representative.

See also:
- To Switch On the Printer, p.74
- Printer, p.22

2.1.5. Reagents Controls

Follow this procedure to control reagents levels and expiration dates.

Access: ***Main screen*** > ***Analyzer (tab)***

1. Check the level of each reagent.
2. Check the expiration date of each reagent.
3. If needed, replace the reagent. See *Maintenance and Troubleshooting* > *Reagents Replacement* chapter.

See also:
- Reagents Replacement, p.159

2.1.6. Startup Failed

Follow this procedure if the instrument startup fails.

1. Check the reagent expiration dates: replace the reagent container if necessary.
2. Re-run a Startup.
3. If the Startup fails again, perform a concentrated cleaning.

See also:
- To Perform a Concentrated Cleaning, p.167
- To Perform a Manual Startup, p.78

2.1.7. Temperature not reached

Follow this procedure when the operation temperature of the instrument is not reached.

Make sure the room temperature is within the temperature range as described in the *Introduction* > *Operational Conditions* chapter.

1. Wait a few minutes to reach the operating temperature.
2. If the temperature still does not increase, please contact your local HORIBA Medical representative.

2.2. Analysis Cycle Problems

- Check if technical problems occur during analysis cycle.
- Control the sampling operations.
- Control the dilution operations.

2.2.1. Sampling Operation Control

Follow this procedure if you detect a problem on sampling.

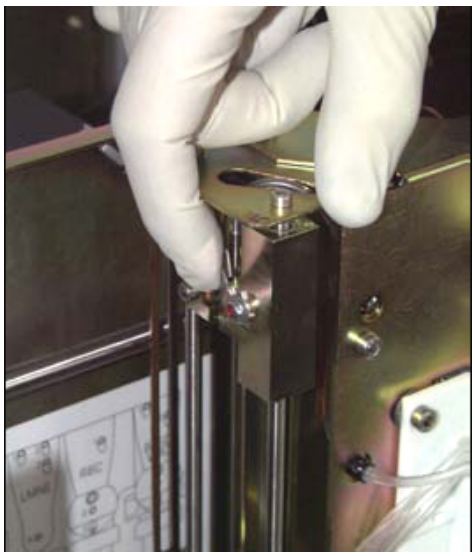
1. Open the pneumatic access door.
2. Check the motion of the needle: go in ***Service*** > ***Mechanical Systems*** > ***Check Motors (tab)*** and click **Sampling Needle**.
   The movements should be smooth and regular.
3. Check that the needle is not bent. If it appears to be bent, replace it.
4. Check the motion of the sampling syringe: go in ***Service*** > ***Mechanical Systems*** > ***Check Motors (tab)*** and click **Sampling Syringe**.
   The movements should be smooth and regular. if not, please contact your local HORIBA Medical representative.
5. Shut the pneumatic access door. Run an analysis and control the blood specimen aspiration.

See also:
- To Check Motors, p.171
- To Replace the Sampling Needle, p.181

2.2.2. To Replace the Sampling Needle

Follow this procedure to replace the sampling needle.

1. Run a **Maintenance Carriage Position** cycle: go in ***Service*** > ***Mechanical Systems*** > ***Maintenance Carriage Position (tab)*** and click **Run**.
2. Switch off the instrument and disconnect the power supply cable.
3. Open the pneumatic access door (right side of the instrument).
4. Lift locker to free the needle.



5. Disconnect the tube from the top of the needle carefully, and replace the needle.

6. Re-assemble in reverse order.

7. Check the motion of the needle: go in ***Service*** > ***Mechanical Systems*** > ***Check Motors (tab)*** and click **Sampling Needle**.
8. Shut the pneumatic access door and run a startup cycle.

When Startup is done, make sure there is no leakage.

2.2.3. Hydraulic Controls

Follow this procedure to check dilution sequences in the chambers.

Access: ***Service*** > ***Mechanical Systems*** > ***Check Motors (tab)***

1. Open the pneumatic access door.
2. **Carriage motion:** Run a **Carriage Syringe** check cycle.
   The carriage should move over the chambers to the right and returns back to its left position. If operations are faulty, try to identify the source of the malfunction.
3. **Sample distribution:** Run a **Sampling Syringe** check cycle.
   The movements of the syringe should be smooth and complete. If operations are faulty, try to identify the source of the malfunction.
4. **Drain:** Run a **Draining syringe** check cycle.
   The movements of the syringe should be smooth and complete. If operations are faulty, try to identify the source of the malfunction.
5. **Drain and Rinse:** Run a ***Service*** > ***Hydraulic Systems*** > ***Drain Chambers*** cycles:
   Check the chambers are drained and rinsed properly. If operations are faulty, try to identify the source of the malfunction.

If any doubt, please contact your local representative.

2.3. Results Problems

Follow the following procedures if your instrument is no repeatable or if inconsistent flags occur.

2.3.1. Problems on all Parameters

Follow this procedure if your instrument is not repeatable on all parameters.

1. Open the pneumatic access door.
2. Check the sampling operations.
3. Control the sampling syringe operations.
4. Control the counting syringe operations.
5. Perform a concentrated cleaning.
   If these operations appear to be correct and that parameters are still not repeatable, please contact your local HORIBA Medical representative.

If the system appears to be operating properly, fresh uncontaminated reagents are used and the precision is within the specifications, the instrument may need to be calibrated as described in Quality Assurance > Calibration chapter.

2.3.2. Problems on RBC, PLT and HCT

Follow this procedure if your instrument is not repeatable or if inconsistent flags occur on RBC, PLT and HCT parameters.

1. Open the pneumatic access door.
2. Control the carriage motion operations.
3. Control the sampling syringe operations.
4. Run a **Check Valves** cycle.
   This controls the correct operation of valve <14>.
5. Perform a concentrated cleaning.
   If these operations appear to be correct and RBC, PLT and HCT parameters are still not repeatable, please contact your local HORIBA Medical representative.

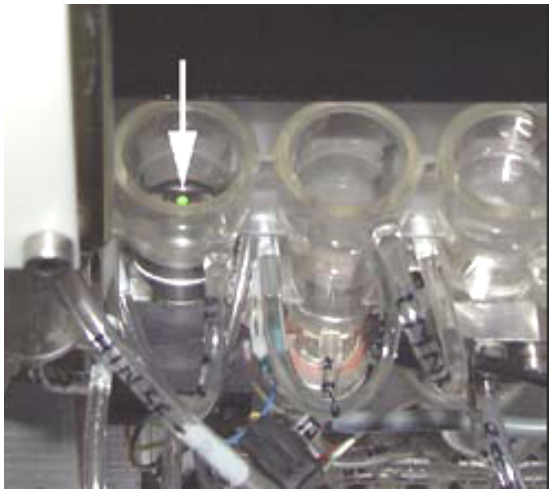
If the system appears to be operating properly, fresh uncontaminated reagents are used and the precision is within the specifications, the instrument may need to be calibrated as described in Quality Assurance > Calibration chapter.

2.3.3. Problems on HGB

Follow this procedure if your instrument is not repeatable or if inconsistent flags occur on HGB parameter.

1. Control the ABX Lysebio / ABX Alphalyse bottle level and expiration date.
   Replace it if necessary. See *Maintenance and Troubleshooting* > *Reagents Replacement* chapter.

2. Open the pneumatic access door and check that the LED is lit when the system power is on.



   If the HGB LED is not lit when the system power is on, please contact your local HORIBA Medical representative.

3. Perform a concentrated cleaning.
   If HGB parameter is still not repeatable, please contact your local HORIBA Medical representative.

2.3.4. Problems on WBC and BAS Parameters

Follow this procedure if your instrument is not repeatable or if inconsistent flags occur on WBC and/or BAS parameters.

1. Open the pneumatic access door.
2. Run a **Check Valves** cycle to control the correct operation of valves <23> and <14>.
3. Perform a concentrated cleaning.
   If these operations appear to be correct and WBC and BAS parameters are still not repeatable, please contact your local HORIBA Medical representative.

2.3.5. Problems on Differential

Follow this procedure if your instrument is not repeatable or if inconsistent flags occur on differential parameters.

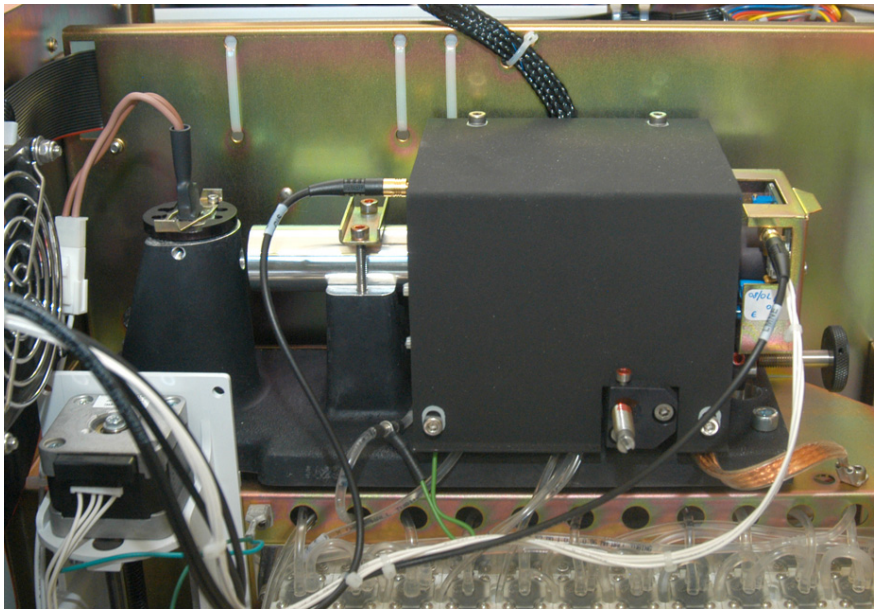
1. Control the ABX Eosinofix bottle level and expiration date.
   Replace it if necessary. See *Maintenance and Troubleshooting* > *Reagent Replacement* chapter.
2. Check that the optical bench lamp works properly when the instrument is on.
   If not, follow the user manual procedure to replace it.
3. Run a cytometer rinse in ***Service*** > ***Hydraulic Systems*** > ***Rinse*** menu.
4. Rerun the specimen.
5. Perform a concentrated cleaning.
   If these operations appear to be correct and Differential parameters are still not repeatable, please contact your local HORIBA Medical representative.

2.3.6. Optical Bench Lamp Replacement

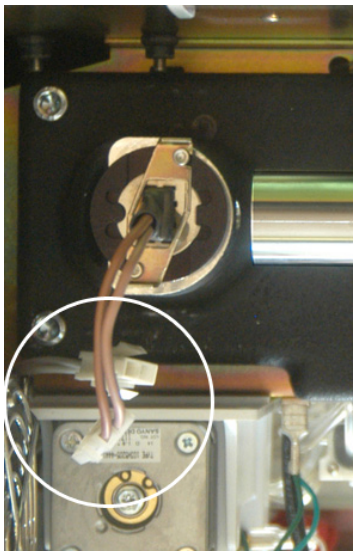
Follow this procedure to replace the lamp of the optical bench.

2mm and 3mm hexagonal keys are required to perform this maintenance.

1. Switch off the instrument and disconnect the power supply cable.
2. Remove the instrument covers.
   See *Maintenance* > *To Remove Instrument Covers* chapter.

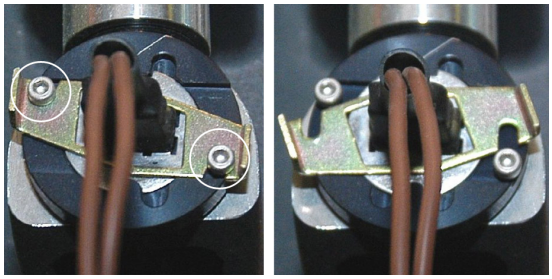


3. Disconnect the lamp supply:



Wait for the lamp to cool down before handling it.

4. Unscrew the lamp fixation screws (a few turns).



5. Turn the lamp and remove it.
6. Replace the lamp by a new one.

Do not touch the bulb with your fingers. This will reduce significantly the shelf life of the lamp. In case of contact, clean the bulb with a solution of 90% alcohol and a soft paper.

7. Put back the fixation system and block the screws.
8. Reconnect the lamp supply.
9. Check that instrument operates normally:
   a. Close the right door.
   b. Connect to power supply and switch on the instrument.
   c. **If the lamp is on**, wait until startup end, switch off the instrument and disconnect power supply cable. Then close the instrument covers, connect to power supply and switch the instrument on.
   d. **If the lamp is off**, check the lamp connection, remove the lamp and check its filament. Try another lamp if possible. If it still does not work, please contact your local HORIBA Medical representative.

See also:
- To Remove Instrument Covers, p.156

3. Error Messages

Printer

Message	Possible cause	Corrective action
The printer is disconnected, switched OFF or has not been selected Defect on printer, make sure there is paper	The printer is out of order	Check printer's connections, switch it on and add paper if needed. If the printer still does not work properly, refer to your printer's user guide.
Printer being used, action impossible	The printer is already operating	Wait for the current printout to complete and restart the request.

Transmission

Message	Possible cause	Corrective action
No ENQ character received on RS232 No ACK character received on RS232 Internal error on RS232 Write error RS232 Timeout overflow on RS232 CRC error Instrument number error Message length error Receiving data error	Defect on transmission operations	Check the RS232 configuration. Please contact your local HORIBA Medical representative.

Calibration

Message	Possible cause	Corrective action
Access Denied	Incorrect password entered by the user	Enter a valid password.
Data not Saved, Value Out of Range	Incoherent value entered by the user	Enter correct value.
XX/XX/XXXX This Date is no longer Valid !	Incoherent date entered by the user	Enter a correct date.
Minimum of 3 Results Required for Calibration	Selected results for calibration calculation not enough	Select at least three results.
Max num. done, Start Cycle Refused	11 results are already recorded in the calibration table	See *Quality Assurance > Calibration* chapter.

Temperature

Message	Possible cause	Corrective action
Temperature out of range	Thermic regulation problem	Please contact your local HORIBA Medical representative.
Heating coil initialization	Operating temperature not reached	Wait for a few minutes.

Reagents

Message	Possible cause	Corrective action
No diluent, check level	Diluent reservoir empty	Replace the diluent container. See *Maintenance and Troubleshooting* > *Reagents Replacement* chapter.
Reagent low level (Reagent name)		Replace the reagent bottle. See *Maintenance and Troubleshooting* > *Reagents Replacement* chapter.
Reagent low level	Message triggered at the end of the startup	Control the reagent levels and replace it if needed. See *Maintenance and Troubleshooting* > *Reagents Replacement* chapter.
Drain sensor time out	Chamber and/or syringe draining problems	Please contact your local HORIBA Medical representative.
Transfer sensor time out	Transfer problem with LMNE matrix sample	Please contact your local HORIBA Medical representative.

Miscellaneous

Message	Possible cause	Corrective action
Emergency stop, run an autocontrol	Blocked motor Incorrect drains Thermal door opened	Control the motor operations in ***Mechanical Systems*** > ***Check Motors*** > ***Service*** menu.
..... not reaching home	Blocked motor	Please contact your local HORIBA Medical representative.
Thermal door opened	Open during a cycle	Close the door and rerun sample.
Illegal time	Incoherent time entered by operator	Enter correct time.
Data not saved, value out of range	Incorrect value entered by operator	Enter correct value.
User password	Password required to carry out an operation	Enter password.
Bad reference position	Mechanical problem	Please contact your local HORIBA Medical representative.
User password	Password required to carry out an operation	Enter a valid password.
Enter an identification	To run an analysis in alphanumerical mode, the identification is mandatory	Enter the identification as described in *Workflow* > *Worklist* chapter.
Language of Pentra changed, please restart the computer and instrument	Language has changed	Restart both instrument and worstation.

Description and Technology

1. Pentra ES 60 Description

1.1. Pentra ES 60 Front Side

1 = Reagents compartment

2 = Status LEDs (red and green)

3 = Start bar

4 = Sampling needle

1.2. Pentra ES 60 Back Side

1 = Diluent input / Waste output

2 = Peripherals connections

3 = Instrument serial label

4 = Switch On / Off

5 = Power supply connection

1.3. Mechanical and Hydraulic Modules

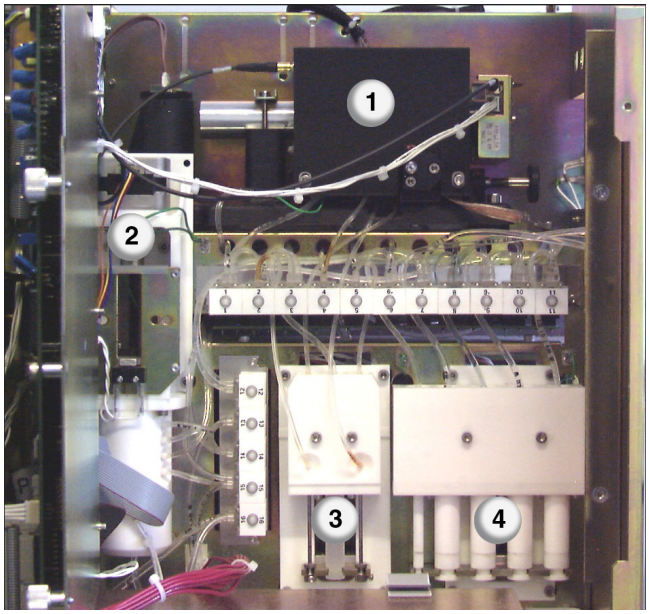
1 = **Sampling carriage**: Ensures needle positioning for the different sampling stages and distribution, and supports the sampling syringe and the blood distribution.

2 = **Sampling syringe**: Distributes portions of the specimen into the dilution chambers, and takes the sample from the first dilution and distributes it into the RBC/PLT chamber.

3 = **Counting assembly**: Receives the different rinsings and dilutions, regulates the temperature of dilutions, and provides the dilutions for RBC/PLT, HGB, WBC/BASO and LMNE.

4 = **Draining syringe**: Drains the chambers, bubbles the mixtures, transfers (by vacuum) the LMNE specimen from the LMNE chamber to the injector of the optical flowcell.

5 = **Diluent tank**: Contains diluent for an analysis cycle, prevents diluent degassing as it is being aspirated by the syringes, and is vacuum filled by the counting syringe.



1 = **Optical bench**: Ensures the support and adjustment of the flowcell, lamp, and optical and electronic elements.

2 = **Counting syringe**: Ensures the vacuum for the WBC and BAS counts, ensures the vacuum for the RBC and the PLT counts, and ensures the vacuum for filling the diluent tank with diluent.

3 = **LMNE Syringe assembly**: Ensures the correct proportioning of the stop diluent in the LMNE chamber, injects the specimen into the flowcell, and injects the interior and exterior sheath into the flowcell.

4 = **Reagent Syringe assembly**: Ensures the correct proportioning of the reagents:

- Lysing reagent for hemoglobin (ABX Lysebio / ABX Alphalyse)
- Cleaning reagent (ABX Cleaner)
- Lysing reagent for DIF count (ABX Eosinofix)
- Diluent used for the dilutions (ABX Diluent)
- Lysing reagent for WBC/BAS (ABX Basolyse II)

Main board: Located on the left side of the instrument, the board is fastened onto a door in order to allow access to the fluidic modules.

Main functions of the board:

- Amplifies, processes and counts the following signals:
  - Resistive signals and LMNE optical signals
  - RBC signal
  - PLT signal
  - WBC/BAS signals
- Measures hemoglobin
- Pilots the motorised elements

Be careful not to disconnect the flat cables while opening the board support panel.

---

2. Measurement Principles

2.1. Multi Distribution Sampling System (MDSS)

CBC mode
In CBC mode, 30µl of whole blood is aspirated then delivered with reagents into chambers as follows:

1 = Diluent

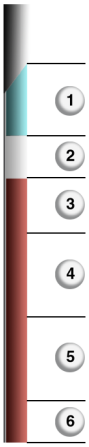
2 = Air

3 = 7µL discarded

4 = 10µL for the BAS/WBC count

5 = 10µL for RBC/PLT dilution

6 = 3µL discarded



DIF mode
In DIF mode, 53µl of whole blood is aspirated, then delivered with reagents into chambers as follows:

1 = Diluent

2 = Air

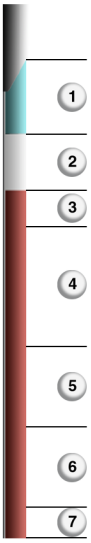
3 = 5µL discarded

4 = 25µL for the LMNE matrix

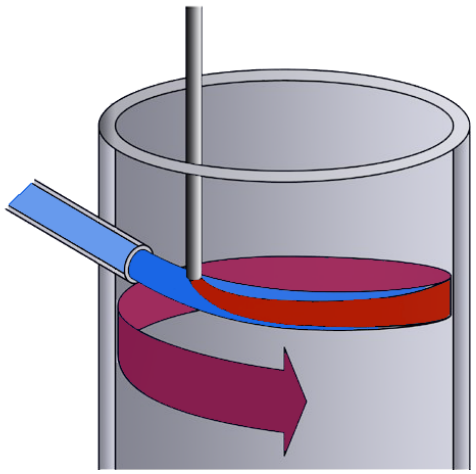
5 = 10µL for the WBC/BASO count

6 = 10µL for the first RBC/PLT dilution and the HGB measurement

7 = 3µL discarded



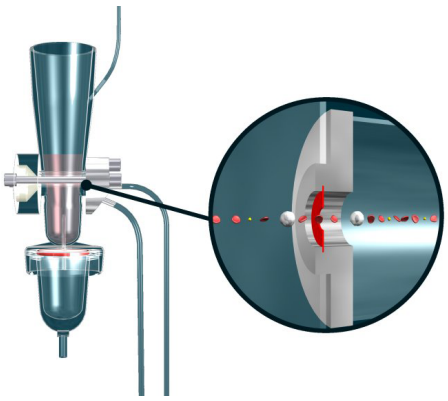
Specimen distribution in the chambers is carried out in a tangential flow of reagent which allows perfect mixing of the dilution and avoids any viscosity problems (this multi distribution in a reagent flow is HORIBA Medical patent).



2.2. Red Blood Cells and Platelets Detection

2.2.1. Detection Principles

- Measurement of impedance variation generated by the passage of cells through a calibrated micro aperture.
- The specimen is diluted in an electrolytic diluent (current conductor) and pulled through the calibrated micro-aperture. Two electrodes are placed on either side of the aperture. Electric current passes through the electrodes continuously.
- When the cell passes through the aperture, electric resistance between the two electrodes increases proportionately to the cell volume.



1 = Voltage peaks for RBC and PLT

- The generated impulses have a very low voltage, which the amplification circuit increases, so that the electronic system can analyze them and eliminate the background noise.
- **Results**: Number of cells counted per volume unit X calibration coefficient.

RBC histogram (Distribution curves on 256 counting channels from 30 fL to 300 fL).

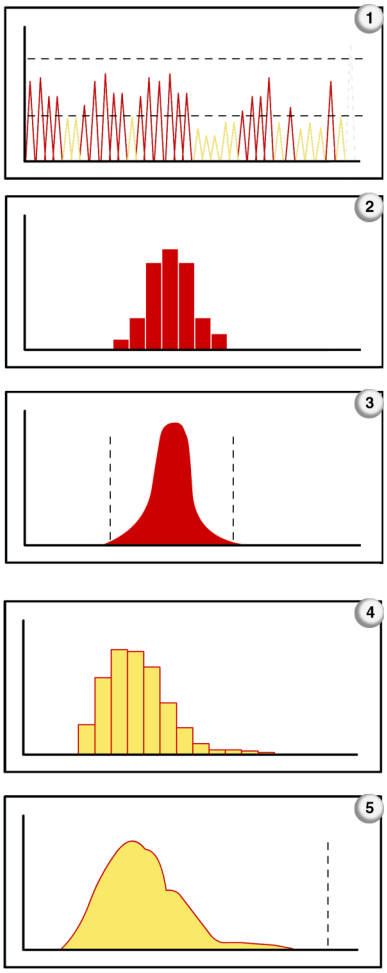
2 = Analogue conversion for RBC

3 = Data integration and plotting of RBC distribution curve

PLT histogram (Distribution curves on 256 channels from 2 fL to a mobile threshold. This threshold moves according to the microcyte population present in the analysis area).

4 = Analogue conversion for PLT

5 = Data integration and plotting of PLT distribution curve



2.2.2. Technical Characteristics

- Method: impedance
- Aperture diameter: 50 µm
- Temperature of reaction: 35°C
- Count vacuum: 200 mb
- Count period: 2 x 5 s
- Initial blood volume: 10 µL
- Volume of ABX Diluent: 2500 µL
- Final dilution rate: 1/10000(two successive dilutions are carried out)

Primary dilution for RBC and PLT:

- Blood 10 µL
- Volume of ABX Diluent: 1700 µL
- Dilution: 1/170

Secondary dilution for RBC and PLT:

- Dilution: 42,5 µL (from the primary dilution)
- Volume of ABX Diluent: 2500 µL
- Dilution: 1/58.8

Final dilution: 1/170 x 1/58.8 = 1/10000

2.3. Hemoglobin Measurement

2.3.1. Measurement Principles

- **Alphalyse**: This reagent breaks down the RBC cell membrane and releases the Hemoglobin within the cell. The hemoglobin, released by the lysing reagent, combines with the Potassium cyanide from the lysing reagent to form a chromogenous cyanmethemoglobin compound. This compound is then measured through the optical part of the first dilution chamber by way of spectrophotometry at a wavelength of 550nm.
- **Lysebio**: Reagent for erythrocyte lysis and cyanide-free determination of hemoglobin. By addition of agent of lysis, hemoglobin is released. All the heme iron is oxidized and stabilized. Oxidation resulting complexes are quantified by spectrophotometry at a wave length of 550nm.

2.3.2. Technical Characteristics

- Method: Photometry
- Wavelength: 550 nm
- Temperature of reaction: 35°C
- Blood volume: 10 µL
- Volume of ABX Diluent: 1700 µL
- Volume of ABX Lysebio / ABX Alphalyse: 400 µL
- Complement of ABX Diluent: 400 µL
- Final dilution rate: 1/250

Final HGB result represents: absorbance value obtained **X** coefficient of calibration.

2.4. Hematocrit Measurement

All the RBC pulses are grouped into various sizes. Each group pulse height is then averaged. All the pulse height averages are then averaged one final time for a mean average of all the RBC pulse heights. This function is a numeric integration of the MCV.

The HCT results are given as a percentage of this integration.

2.5. RDW Calculation

The RDW (Red cell Distribution Width) is used to determine erythrocyte abnormalities linked to Anisocytosis. The RDW enables to follow the evolution of the width of the RBC histogram regarding the number of cells and their average volume.

The RDW is also a calculation from the RBC histogram.

Calculations are as followed:

- **RDW = (K X SD) / MCV**

With:

- K = system constant
- SD = Standard Deviation according to statistical studies on cell distribution within the RBC histogram.
- MCV = Mean Corpuscular Volume of erythrocytes

2.6. MCV, MCH, MCHC Calculation

- MCV (Mean Cell Volume) is calculated directly from the entire RBC histogram.
- MCH (Mean Cell Hemoglobin) is calculated from the HGB value and the RBC count.
- The mean hemoglobin weight in each RBC is given by the formula:
  - **MCH (pg) = HGB/RBC x 10**

- MCHC (Mean Corpuscular Hemoglobin Contained) is calculated according to the HGB and HCT values. Mean HGB concentration in the total volume of RBC is given by the formula:
  - **MCHC (g/dL) = HGB/HCT x 100**

2.7. MPV Measurement

The MPV (Mean Platelet Volume) is directly derived from the analysis of the platelet distribution curve.

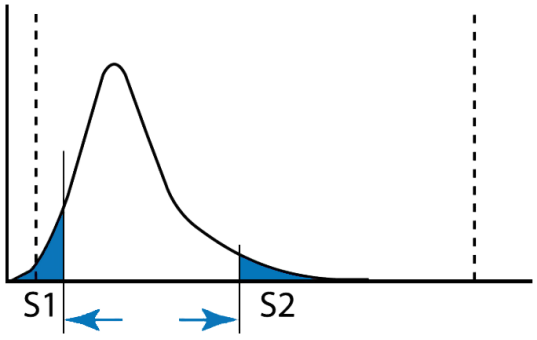
2.8. Plateletcrit Calculation

Plateletcrit (or thrombocrit) is calculated according to the formula:

Pct% = PLT (10^3/mm^3) x MPV (μm^3) / 10 000

2.9. PDW Calculation

PDW (Platelet Distribution Width) is calculated from the PLT histogram.
The PDW is represented by the width of the curve between 15% of the number of platelets starting from 2 fL (**S1**), and 15% of the number of platelets beginning with the variable top threshold (**S2**).



2.10. White Blood Cells / Basophils Count

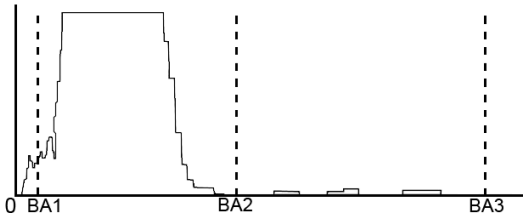
Counting principle

The WBC count is carried out twice by two different sensors:

- In the WBC/BAS chamber at the same time as the Basophils count.
- In the optical chamber during the acquisition of the LMNE matrix.

The reference count is the one obtained in the WBC and Basophils count chamber.

- Detection principle is the same as for RBC. Differentiation betwen Basophils and other leukocytes is obtained by means of the ABX Basolyse II specific lysing action.
- All the WBCs are counted between the electrical thresholds, from <0> to <BA3>. The basophils are located from threshold <BA2> to threshold <BA3>.



Results

WBC: The number of cells counted within a specified amount of time per volume **X** WBC coefficient of calibration.

BAS: The number of cells counted within a specified amount of time per volume **X** the WBC calibration coefficient in a percentage as to the total number of leukocytes (Basophils and WBC nuclei).

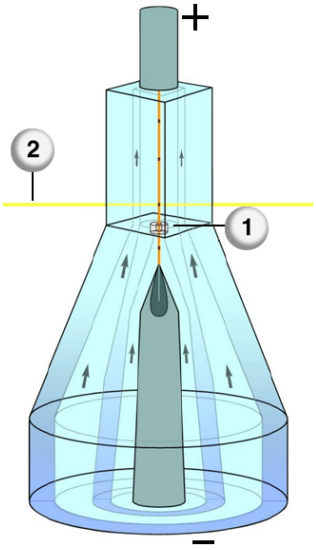
Technical characteristics for WBC/BAS counts	
Initial blood volume	10 µl (CBC or CBC/DIF)
Volume of ABX Basolyse II	2000 µl
Temperature of reaction	35°C
Method	Impedance

Technical characteristics for WBC/BAS counts	
Aperture diameter	80 µm
Count vacuum	200 mb
Count period	2 X 6 seconds
Final dilution rate	1/200

2.11. LMNE Matrix Count

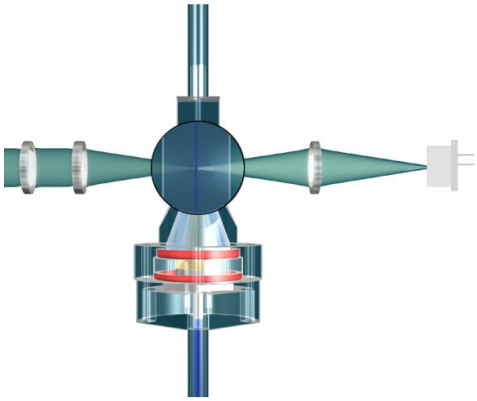
Differential count in the flowcell is based on three essential principles:

- The Double Hydrodynamic Sleeving System «DHSS» which allows a linear flow of the cells through the light path (HORIBA Medical patent).
- The cell volume, which is measured by electrical current (*impedance changes*). **1**
- The measurement of transmitted light at a 0° angle, which allows a measured response according to the internal structure of each cell and its absorbance, as unabsorbed light passes through the spaces in the nuclear material of each cell. This is known as diffused light. **2**
- 25µL of whole blood is delivered to the LMNE chamber in a flow of ABX Eosinofix. This reagent lyses the RBC, stabilizes the WBC in their native forms and stains the eosinophil nuclei with a specific coloration.
- The solution is then stabilized with ABX Diluent and transferred to the flowcell. Each cell is measured both in absorbance (cytochemistry) and resistivity (volume).



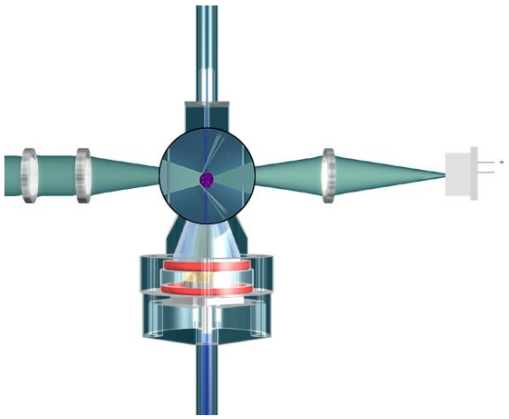
Technical characteristics for WBC counts during acquisition of the matrix	
Initial Blood volume	25 µL
Volume of ABX Eosinofix	1000 µL
Volume of ABX Diluent	1000 µL
Incubation duration	12 s
Temperature of reaction	35°C
Method	Impedance with hydrofocus
Aperture diameter	60 µm
Flow diameter	42 µm
Injection duration	12 s
Injected volume	72 µL
Final dilution rate	1/80

No cell in the flowcell



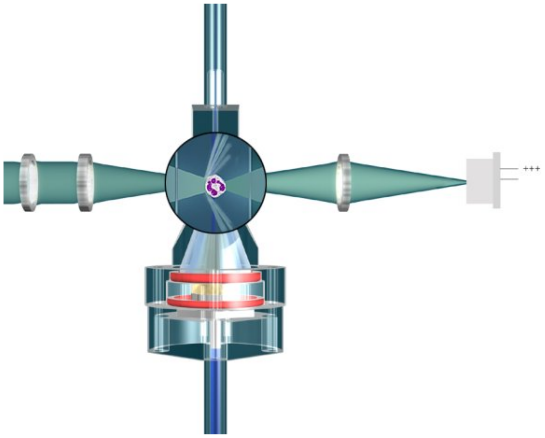
Baseline

Poorly-stained (agranular) cell in the flowcell



High absorbance

Hyper segmented with complex granularity and staining



Low absorbance

Results

From the Absorbance and Resistive measurement of the leukocytes, a matrix is developed with cell volumes on the X-axis and optical transmission on the Y-axis. Study of the matrix image allows a clear differentiation of 4 of the 5 leukocyte populations. Due to the low percentage of Basophils in comparison to the rest of the leukocytes, they have a separate measurement and their own matrix.

Cells description

- **LYMPHOCYTES**: The lymphocyte is a very small round shaped cell with condensed cytoplasm and large nucleus. This cell is normally positioned in the lower part of the Y-axis, as well as the lower part of the X-axis because of its small size. The far left side of the lymphocyte area (LL) should normally be empty. Any detection of cells in the LL area indicates Small lymphocytes, Platelet aggregates, NRBCs (Nucleated Red Blood Cells), and/or improperly adjusted flowcell alignment. Background noise may also be detected in this area if the interference is important.
- **MONOCYTES**: The monocyte is a very large irregular shaped cell with large convoluted nuclei. The nucleus contains folds and sometimes vacuoles. The cytoplasm is also large with non-granular intra-cellular material. This cell does not scatter or absorbs a large amount of light when passing through the flowcell. It is positioned in the lower part of the Y-axis. Because the monocyte is a large cell, it is positionned on the right side of the X-axis.
- **NEUTROPHILS**: The neutrophil is larger in size than the lymphocyte. It contains granular material in its cytoplasm along with a segmented nucleus. Due to these cellular features, more light will pass through neutrophils in the flowcell. As a result, neutrophils go higher on the Y-axis and spread along the X-axis according to their maturity. Hyper-segmentation and increased granules place this population higher along the Y-axis.
- **EOSINOPHILS**: The eosinophil is somewhat like the neutrophil. It contains granular material and segmented nuclei within the cytoplasm. The granular material is colorized with a reagent before passing through the light beam in the flowcell. Due to the colorization action of the reagent, the eosinophils are placed in the highest part of the Y-axis. Hyper-segmentation and increased granules place this population in the top-right area of the matrix.

Additional parameters: LIC (Large Immature Cells) and ALY (Atypical Lymphocytes) complete the matrix spectrum of cellular placement.

Immature granulocytic cells are detected by their larger volumes and by the increased granules, which allow more light to pass through the cells and increase the intensity of scattered light. Therefore, cells such as metamyelocytes will be found to the right of the neutrophils and almost at the same level. Myelocytes and promyelocytes will be found on the far right of the matrix in the saturation position. The metamyelocytes, myelocytes, and promyelocytes will all be classed as (LIC) and there given results will be included in the neutrophil value. The Blast cells will be generally located to the right of the monocyte population and, as such, will increase the (LIC) count. Small blast cells will be found between the normal lymphocyte and monocyte populations (ALY).

Platelet aggregates and debris from RBC cell fragments are found in the background noise area, at the bottom-left corner of the matrix. Most of the cell population thresholds are fixed and give the normal limits for the normal leukocyte morphologies. Changes in the morphology of a specific population will be indicated on the matrix by a shift in the corresponding population.

A Blast alarm is generated from increased counts within the (LIC) area; this is correlated with the Blast detection on the Basophil histogram.

Large lymphocytes are usually detected in the (ALY) area, where reactive lymphoid forms, stimulated lymphocytes, and plasmocytes are also found.

Glossary

1. Glossary of Terms

Accuracy

Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.

Analysis (Field of)

Interval of concentrations (or other quantities) of an analyte for which the technique is applicable without modification. Its evaluation requires the establishment of linearity limits and (possibly) of the detection limit of the technique. Synonym: “Field of measurement, range of measurement”.

Analyte

Component, substance, material to be measured in a possibly complex environment.

Analytical sensitivity

In compliance with the Common Technical Specifications (CTS), the «analytical sensitivity» refers to the limit of detection, i.e. the small quantity of target marker that can be detected with precision.

Analytical specificity

The capacity of the method to determine only the target marker.

Bias (ISO 3534-1)

Difference between the mathematical prediction of the results of the analysis and the accepted reference value.

Background count

Measure of the amount of electrical or particle interference.

Calibration

Set of operations to establish, under specified conditions, the relationship between the values of the quantity indicated by a measuring instrument or a measurement system or the values represented by a materialized measurement or by a reference material, and the corresponding values of the quantity given by standards.

Calibration factors

These are correction factors that the system uses to fine-tune instrument accuracy.

Calibrator

A (reference) material (e.g., solution, suspension) or device of known quantitative/qualitative characteristics (e.g., concentration, activity, intensity, reactivity) used to calibrate, graduate, or adjust a measurement procedure or to compare the response obtained with the response of a test specimen/ sample (NCCLS H38-P)

Carry-over

Amount of blood cells remaining in diluent following the cycling of a blood sample (in percent).

Cell control

Preparation made of human blood with stabilized cells and surrogate material used for daily instrument quality control.

Certified reference material

Reference material, accompanied by a certificate, of which one (or several) value(s) of the property(ies) is (are) certified by a procedure that establishes its association with an exact undertaking of the unit in which the property values are expressed and for which each certified value is accompanied by an uncertainty with a known level of confidence.

Chemical specificity, specificity

Property of an analytical method to selectively determine the concentration of the component(s) that it is designed to measure.

Coefficient of variation (CV) ISO 3534-1

For a non-negative character, ratio of the standard deviation to the mean.

Contaminant (Effect)

Undesirable effect, resulting from contamination. Most commonly, this is the effect exerted by a serum on that which follows or precedes it. It may also arise from contaminating effects between reagents.

Control

Substance used for monitoring the performance of an analytical process or instrument.

Conventionally true value (of a quantity)

Value attributed to a specific and recognized quantity, sometimes by convention, as the representative for an appropriate uncertainty for a given use.

Correction

Value that is algebraically added to the raw result of a measurement to compensate for a systematic error.

- the correction is equal to the opposite of the estimated systematic error
- since the systematic error cannot be precisely known, the compensation cannot be complete.

Correlation coefficient

Quotient of the covariance of two characteristics by the product of their standard-deviations. It expresses the possible relationship between two variables that are known to be independent. Its value must only be tested in comparison with zero according to a chosen risk. It is usually of no interest in technical comparisons.

Default setting

Original factory setting.

Deviation

Value minus its reference value

Error

Result of a measurement minus a true value of the measurand (Bias).

Error of trueness (of a measuring instrument)

Systematic indication error of a measuring instrument. The trueness error is normally estimated by taking into account the mean of the indication error on an appropriate number of repeated observations.

Exactitude (Precision)

Closeness of the agreement between the result of a measurement and the true value of the measurand.

Detection limit (XP T 90-210)

The smallest quantity of an analyte to be examined in a sample that can be detected and considered as being different from the value of the blank (with a given probability), but not necessarily quantified. Two risks need to be taken into account:

- the risk of considering the substance present in the sample when in fact its quantity is nil.
- the risk of considering a substance absent when in fact its quantity is not nil.

Drift

Slow variation over time of a metrological characteristic of a measuring instrument.

Femtoliter (fL)

One quadrillionth (10^{-15}) of a liter.

Flag

On printouts or screen, letters or symbols that appear next to a parameter result to indicate specific conditions.

Grading

Material positioning of each marker (possibly of certain principal markers only) of a measurement instrument according to the value of the measurand.

Linearity (XP T 90-210)

Capacity of a method of analysis, within a certain interval, to provide a value of information or results proportional to the quantity of analyte to be assayed in the laboratory sample. This proportionality is expressed using a previously defined mathematical expression. The limits of linearity are the experimental limits of quantities between which a linear standard model can be applied with a known level of confidence (generally taken as being equal to 1%).

LIS

Laboratory Information System

Lot number

Manufacturer's code that identifies products such as reagents, controls or calibrators.

Matrix

Environment in which the analyte is found.

Mean, m

The sum of observations divided by their number. Unless otherwise indicated, the term "mean" designates the arithmetic value.

Measurement

A series of operations whose aim is to determine a value of a quantity.

Measurand

Specific quantity subjected to measurement.

Noise

Corresponds to random variations of the measurement signal for a given level. It is measured by the standard deviation of a series of at least 30 measurements of the signal, at the level in question.

Operating range

Range of results over which the instrument displays, prints and transmits data.

Parameter

Component of blood that the instrument measures and reports.

Performance criteria

Parameters characterizing the analytical procedure (linearity, repeatability, trueness, etc.)

Platelet concentrate

Labile blood product, composed of platelets, produced by blood bank centers and intended for transfusion.

PRP

Cellular suspension in the plasma, high platelet concentration obtained by sedimentation from a whole blood sample to determine on the hematology analyzer the platelet count in the presence of a contaminating microcytic RBC population.

Quality control (QC)

Comprehensive set of procedures that a laboratory establishes to ensure that the instrument is working accurately and precisely.

Quantification limit (XP T 90-210)

The smallest quantity of an analyte to be analyzed in a sample that can be determined quantitatively under the experimental conditions described in the method with a defined variability (determined coefficient of variation).

Reagent blank

Corresponds to the signal resulting from the reagent(s) used during an assay or a measurement of catalytic activity. The sample is replaced by an equal volume of an appropriate solvent.

Reference material (Calibrator, reference values)

Material or substance of which one (or several) value(s) of the property(ies) is (are) sufficiently homogeneous and well-defined to enable it to be used to calibrate a piece of equipment, evaluate a measuring method, or attribute values to materials.

Reference technique (reference method)

Internationally recognized technique whose accuracy has been evaluated in comparison with a definitive technique or following a complete and detailed study. The principle, reagents, apparatus, operating procedure, and the calculations are precisely defined.

Reference values

Results obtained for a given component in a reference population whose individuals are exempt from disease or treatments that may alter their values. The reference values may vary, notably according to the geographic origin, sex, and age of individuals. They are usually expressed as a function of lower and upper limits that have been determined via statistical studies. They may be established by the biologist, according to the analytical techniques used, or possibly verified when data from scientific publications is used. The expression «reference value» is preferable to «usual value» or «normal value».

Reliability (Precision)

Aptitude of a measuring instrument to give very similar indications during the repeated application of the same measurand under the same measurement conditions.

Repeatability

Closeness of the agreement between the results of successive measurements of the same measurand, measurements undertaken entirely in the same conditions of measurement.

Reproducibilty

Closeness of the agreement between the results of measurements of the same measurand, measurements undertaken under a variety of measurement conditions.

Result of a measurement

Value attributed to a measurand, obtained by measurement.

Specimen

To avoid any confusion with the term sample (in the following context: group of individuals from a population), it is preferable to use the term specimen to designate a biological sample (blood specimen, urine specimen, etc.)

Specimen blank

Signal resulting from certain properties of the environment in which the analyte is found. Ideally, it results from a signal measurement undertaken under the conditions of the reaction on the sample that does not contain the analyte, or on the sample following elimination or inactivation of the analyte.

Standard

Materialized measurement, measuring apparatus, reference material or measurement system designed to define, undertake, store, or reproduce a unit or one or several values of a quantity to serve as a reference.

Standard deviation (SD)

Measure of variation within a group samples or within a population.

Standard error of the mean, S.E.M

Statistical parameter indicating the dispersion of values at the level of the mean of a series of measurements.

Standard uncertainty

Uncertainty of the result of a measurement expressed as a standard deviation.

Shutdown cycle

Cleans the instrument’s fluidic lines and apertures to help prevent residue build-up.

Startup cycle

Ensures that the instrument is ready to run; includes performing a background test.

Trueness

Aptitude of a measuring instrument to give results that are exempt from systematic error.

Uncertainty

Parameter associated with the result of a measurand that characterizes the dispersion of values that could reasonably by attributed to the measurand.

Validation (analytical and biological)

This is the set of procedures used to ensure that a technique has the required reliability to meet the quality control requirements in the state of the art. The validation generally comprises two stages: a technical validation and a biological validation. The first consists, following a series of assays, of verifying with appropriate controls that the principal errors have been maintained within acceptable limits. The second involves ensuring the coherence of the result in its clinical context, by comparing it with any previous results and with the results of other analyses requested for exploring the same function.

Validation (Validation of methods)

Verification process that involves comparing the values of performance criteria, as determined during the characterization study or experimentation phase (test phase) of the analytical method, to those initially expected or assigned (acceptable limits, objectives to be attained), and then to declare whether the method of analysis is valid or not (see definition of the standard EN ISO/CEI 17025, §5.4.5.1).

Validation technique

A validation technique is a technique that, following exhaustive study (literary and experimental research), is designated for use as a reference of exactitude, for comparative assays or titrations of control sera. It is chosen from amongst the reference techniques or selected by national or international companies, or by consensus. It has acceptable and recognized levels of precision and practicability. It should be described in detail, tested in several laboratories, and include the definition of the equipment, controls required on the apparatus, the description of the various reagents and specifications, the conditions of storage and use of the reagents, the operating procedure, the calibration or standardization method, the nature of the calibrators, and the control method.

Verification (EN ISO 10012)

Confirmation by examination and establishment of proofs that the specified requirements have been met.

Whole blood

Non-diluted blood (blood and anticoagulant only).

Index